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Physical and functional outcomes of total knee arthroplasty: a comparison of two surgical approaches

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BPhty

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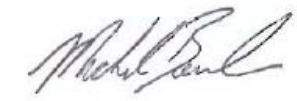

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MGB was involved in conception and design of the review, searched databases and located articles, analysed and interpreted findings and prepared the manuscript. PJB, PAD and PLF independently reviewed the articles and manuscript. GAJ was involved in conception and design of the review, analysis and interpretation of findings and review of the manuscript. TGR was involved in conception and design of the review, analysis and interpretation of findings and review of the manuscript.

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Bourke, MG. Waller, M. Lumchee, MW. Jull, GA. Russell, TG. Knee osteoarthritis: determining probability of TKA. Queensland Orthopaedic Physiotherapy Network 5th Annual Conference Day. 11 September, 2009. Brisbane, Queensland.

Bourke, MG. Acute Physiotherapy Management of Total knee arthroplasty. Queensland Orthopaedic Physiotherapy Network Inaugural Conference Day. 22 September 2006. Brisbane, Queensland.

Poster presentations

Bourke, MG. Buttrum, PJ. FitzPatrick, PL. Dalton, PA. Dodsworth, J. Johnstone, P. Kennedy, R. Nielsen, G. Vicenzino, W. Russell, TG. An evaluation of the clinical outcomes of the subvastus versus the medial parapatellar approach to total knee arthroplasty – a prospective randomised clinical trial. Queensland Orthopaedic Physiotherapy Network 2nd Annual Conference Day. 7 September, 2007. Brisbane, Queensland.

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Abstract

Total knee arthroplasty (TKA) is an effective procedure for the management of late stage knee osteoarthritis (OA), and one which is increasing in demand. There are numerous surgical approaches of which the subvastus approach (SVa) and medial parapatellar approaches (MPa) are two options. Despite claims that SVa provides superior outcomes to the more common MPa, there has been little investigation into the physical and functional outcomes associated with each approach or their relative effect on patellar vascularity. Studies that have compared the approaches contain methodological flaws affecting confidence in the conclusions drawn. Indications for when a patient requires referral to an orthopaedic surgeon for TKA are also unclear. A better understanding of how surgical approach affects outcomes, and when a patient should be referred to an orthopaedic surgeon for review of their knee OA may optimise outcomes and improve efficiencies in patient selection.

The aims of this thesis were to address deficits in the literature concerning the relative merits of the MPa and SVa in TKA, and the clinical indications for TKA. The first aim was to conduct a systematic review of the literature to compare the two approaches to determine whether one had superior outcomes over the other. The second aim was to conduct a randomised controlled trial comparing the physical and functional outcomes associated with MPa and SVa in TKA in the short, and medium (18 month) terms. The third aim was to conduct a sub-study to determine whether the SVa maintained better patellar vascularity than the MPa, thereby reducing the risk of avascular necrosis (AVN) and anterior knee pain. The final aim was to conduct modelling to determine if physical measures, patient-assessed scoring instruments and/or clinical rating systems could be used as indicators for the timely referral of patients to an orthopaedic surgeon.

Results of the systematic review revealed insufficient or equivocal evidence supporting the SVa over the MPa. The methodological quality of most studies was poor as they either failed to randomise appropriately, adequately conceal allocation, report complications, define inclusion and exclusion criteria, or define outcomes. The use of heterogeneous outcomes prevented pooling of data for meta-analysis which may have resulted in stronger conclusions.

The randomised controlled trial was designed and conducted to address the limitations that were highlighted by the systematic review. The American Knee Society Score (AKSS) was used as the primary outcome from pre-operatively to 18 months. Secondary outcomes were knee pain, the Oxford Knee Score, three metre Timed Up and Go test, knee flexion, extension, quadriceps lag on straight leg raise (SLR), days to SLR, knee girth, length of hospital stay, operation duration, tourniquet time and surgeon perceived level of difficulty with the approach. Results of the

randomised controlled trial, using linear mixed modelling for the analysis of continuous variables, revealed no difference on any outcome at any time-point between the SVa and MPa groups. The exceptions were earlier SLR in the SVa group, better AKSS Objective scores on day 1 post-operatively in the SVa group but overall better AKSS Functional scores at 12 and 18 months for the MPa group. While earlier SLR was observed in the SVa group, the surgeons perceived this approach as more difficult.

Patellar vascularity was assessed using two novel methods developed for this trial from nuclear medicine imaging techniques. These were the pat:fem ratio, which is a ratio of photon counts in the patella compared to a standardised region of interest on the femur; and the five-point Bone Vascularity Scale (BVS), which is a new quantitative method for analysing images of vascularity. There was no difference in patellar vascularity between groups on either the pat:fem or the BVS measures.

The model developed to assist primary health care providers to decide when to refer a patient with knee OA to an orthopaedic surgeon, incorporated the AKSS Functional score and knee flexion range of motion (AKSSFun/flexion) and predicted group allocation accurately 95% of the time (Odds Ratios: 1.28 to 3.40 for 1º and 5º parameter changes in flexion respectively).

This research program found, on balance, no substantive evidence supporting the superiority of the SVa over the MPa over a range of physical, functional and vascularity measures. The findings therefore refute previous supposition and claims of advantages the SVa provides over the MPa.

Keywords

arthroplasty, replacement, knee, subvastus, medial parapatellar, patellar vascularity, probability

Australian and New Zealand Standard Research Classifications (ANZSRC)

110314 Orthopaedics 70%, 110317 Physiotherapy 20%, 110313 Nuclear Medicine 10%

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Abbreviations

AKSS	American Knee Society Score
AKSSFun	AKSS functional score
AKSSFun/extension	AKSS Functional score and knee extension range of motion
AKSSFun/flexion	AKSS Functional score and knee flexion range of motion
AKSSObj	AKSS objective knee score
ANOVA	Analysis of variance
AVN	Avascular necrosis
BMI	Body mass index
BVS	Bone Vascularity Scale
CONSORT	Consolidated Standards of Reporting Trials
DGA	Descending geniculate artery
EuroQol	European quality of life questionnaire
HSS	Hospital for Special Surgery (score)
HTO	High tibial osteotomy
ILG	Infero-lateral geniculate artery
IMG	Infero-medial geniculate artery
LCS	Low-Contact Stress
LMM	Linear mixed modelling
MCID	Minimal clinical important difference
MIS	Minimally invasive surgery
MOS	Medical outcomes study
MPa	Medial parapatellar approach
MUA	Manipulation under anaesthetic
NAS	Numerical Assessment Scale
NSAIDs	Non-steroidal anti-inflammatory drugs
OA	Osteoarthritis
OKS	Oxford Knee Score
PCL	Posterior cruciate ligament
PDA	Personal digital assistant
PFC	Press-fit condylar
ROI	Region of interest
ROM	Range of motion
SF-36	36-Item Short Form Health Survey

SLG	Supero-lateral geniculate artery
SLR	Straight leg raise
SMG	Supero-medial geniculate artery
SVa	Subvastus approach
TENS	Transcutaneous electrical nerve stimulation
TKA	Total knee arthroplasty
TUG	Timed Up and Go test
UKA	Unicompartmental knee arthroplasty
UHMW	Ultra-high-molecular-weight
WOMAC	Western Ontario and McMaster Universities index of osteoarthritis

1 Introduction

1.1 Background

Total knee arthroplasty (TKA) for the management of knee osteoarthritis (OA) has increased by 54.9% per annum since 2003 (Australian Orthopaedic Association, 2011). More than 44,000 knee-related prosthetic procedures were performed in Australia in 2009, which is a 7.6% increase on the previous year. Of these, 85.4% were primary TKAs (Australian Orthopaedic Association, 2011). The demand for TKAs is expected to increase in future years alongside an increase in the prevalence of knee OA (National Institute of Health, 2004). TKA has proven to be effective as a treatment for end stage knee OA and is a well established intervention with favourable outcomes relating to decreased pain and improved function (Callahan et al., 1994, 1995; Dieppe et al., 1999).

There are many considerations a surgeon must address when planning for and performing a TKA. These considerations include but are not limited to: the surgical approach to the joint, the type of prosthesis, the use or not of bone cement to fixate the prosthesis, the use of wound drains and tourniquets, thromboprophylactic management, the method of anaesthesia, and types of wound dressings (Solomon et al., 2010). With limited health resources, a plethora of options, and a paucity of empirical evidence for combinations, there is a need to determine which options provide better physical and functional outcomes.

One of the key options requiring investigation is the surgical approach to the joint. There are numerous options for the approach, each with its own merits. There is, however, a lack of evidence supporting one over another. The medial parapatellar approach (MPa) is the most common approach and is well described by Stern (2002). It affords excellent exposure as it extends proximally from the superior pole of the patella into the extensor mechanism by 60 to 80mm. The subvastus approach (SVa) is arguably more difficult and accesses the knee under the quadriceps muscle (Hofmann et al., 1991). This surgical approach purportedly affords better outcomes with research demonstrating better quadriceps function (Faure et al., 1993; Cameron, 2001; Roysam et al., 2001; Cila et al., 2002; Weinhardt et al., 2004), and less pain (Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004) when compared to the MPa. There are, however, inconsistent findings on other outcomes. For example, Cameron et al. (2001) reported flexion was better in the SVa by, which did not concur with Roysam et al. (2001) who found no difference. The trend of inconsistencies favouring the SVa is found across other outcomes including blood loss (Faure et al.,

1993; Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004) and length of surgery (Faure et al., 1993; Cameron, 2001; Weinhardt et al., 2004). To address the seeming lack of concordance in the literature, a systematic review which focused on the quality of the methodology of the research that investigated the outcomes of the SVa when compared to the MPa was required. The review found only five studies that compared the relative merits of these two arthrotomies (Faure et al., 1993; Cameron, 2001; Roysam et al., 2001; Cila et al., 2002; Weinhardt et al., 2004) and due to study design limitations including randomisation and blinding concerns, firm conclusions about the superiority of either approach was not possible.

It is biologically plausible that a patient with less pain, better quadriceps function, greater knee range of motion and less blood loss will be independently mobile sooner than someone who is not. As these factors are critical in determining when discharge from hospital is appropriate, it follows that length of stay could be reduced if it were found that the surgical approach to the knee could positively influence these outcomes. Therefore, in order to optimise outcomes and direct resources towards the most efficacious practices for TKA, there is a need to further investigate and define the effect of surgical approach on physical and functional outcomes. As the answer to this question is not clear from the existing literature, a randomised controlled trial comparing the MPa and SVa on both physical and functional outcomes is required. One of the strongest arguments used to support the SVa is the theoretical advantage of improved blood supply achieved by preservation of the patella arterial supply (Hofmann et al., 1991) and the avoidance of subsequent avascular necrosis (AVN), a complication that the SVa purportedly avoids (Hofmann et al., 1991). The effect of the surgical approach on the patency of the geniculate arteries that nourish the patella, and subsequent anterior knee pain requires investigation.

Furthermore, the indications for TKA are not definitively known, with reasons such as pain (Mancuso et al., 1996; Naylor et al., 1996; Hadorn et al., 1997), loss of joint space or joint damage (Mancuso et al., 1996; Hadorn et al., 1997), high patient motivation (Mancuso et al., 1996), functional impairment (Naylor et al., 1996; Hadorn et al., 1997), radiographic severity (Kellgren et al., 1950; Ahlback, 1968; Insall et al., 1989), and problems with care giving (Naylor et al., 1996; Hadorn et al., 1997) all cited as potential indicators. However, there are currently no definitive quantitative criteria to assist primary health care providers, such as physiotherapists, in determining when patients warrant referral to an orthopaedic surgeon for consideration for surgical intervention. Indecision may result in inappropriate referrals, longer waiting times and higher costs. To address these issues, a quantitative method that is based on both functional and objective outcomes is required.

The implications of knowing which approach produces superior physical, functional and vascularity outcomes are numerous. Should the SVa afford better outcomes, there will be an imperative for surgeons to use it for appropriate patients. A reduction in pain and earlier return to function will reduce the burden of recovery on patients and health care systems. Additionally, the long term debilitating effect of anterior knee pain due to AVN may be a complication relegated to surgical history books. Finally, being able to quantify which patients require referral to an orthopaedic surgeon will ensure appropriate and timely referrals resulting in improved patient satisfaction and appropriate use of orthopaedic services.

1.2 Thesis aims

The purpose of this thesis was to investigate whether the SVa in TKA affords better physical and/or functional outcomes than the more commonly performed MPa and to investigate whether either surgical approach influences the incidence of subsequent AVN. In addition, the question of when patients should be referred to an orthopaedic surgeon will be addressed.

Specifically, the aims of this thesis are:

A1: to systematically review current literature comparing the MPa and SVa in TKA to determine whether one has superior outcomes over the other;

A2: to conduct a randomised controlled trial to compare the physical and functional outcomes associated with MPa and SVa in TKA in the short and medium (18 month) terms;

A3: to determine whether the SVa maintains vascularity to the patella better than the MPa, thereby reducing the risk of AVN and anterior knee pain; and

A4: to conduct modelling to determine if physical measures, patient-assessed scoring instruments and/or clinical rating systems could be used as indicators for the timely referral of patients to an orthopaedic surgeon.

1.3 Hypotheses

The hypotheses related to the experimental research (A2–A4) were that:

H1: (i) participants receiving the SVa would experience better early outcomes than those receiving the MPa and (ii) that outcomes would converge by 18 months after surgery;

H2: the SVa would have better outcomes for vascularity and anterior knee pain than the MPa due to the extensive dissection of the patellar arterial blood supply in the MPa; and

H3: a model based on physical and functional measures could be used to quantify when it is appropriate to refer a patient to an orthopaedic surgeon.

1.4 Thesis overview

This thesis first presents a concise summary (Chapter 2) of knee OA and TKA. It includes information about the epidemiology and pathology of OA with a brief outline of conservative management of the osteoarthritic knee. Chapter 2 also outlines indications for TKA and focuses on surgical approaches and complications of TKA. Chapter 3 reports a systematic review of the literature comparing the MPa and SVa in TKA. Chapter 4 reports the details of a randomised controlled trial comparing the SVa and MPa in TKA. Chapter 5 investigates patellar vascularity after TKA using nuclear medicine technologies, and introduces a novel vascularity scoring system. Chapter 6 investigates a model based on physical and functional outcomes to determine when a patient with knee OA should be referred to an orthopaedic surgeon. The discussion (Chapter 7) and conclusion (Chapter 8) address the implications and limitations of the research and future directions for research in this area.

References cited in this body of research are presented as a single list at the conclusion of the thesis, rather than after each chapter (including the published papers) to avoid repetition in their listing.

2 Knee osteoarthritis and arthroplasty

Total knee arthroplasty (TKA) is an effective procedure for obtaining favourable outcomes in the management of late stage knee osteoarthritis (OA) (Callahan et al., 1994). This chapter reviews the incidence, pathology and conservative management of knee OA and discusses TKA from an historical perspective. Surgical approaches in TKA are outlined including the subvastus approach (SVa) and medial parapatellar approach (MPa) upon which a comparison forms the basis of this thesis.

2.1 Epidemiology and incidence of knee osteoarthritis

OA is the most common indication for knee arthroplasty (DeFrances et al., 2006; Australian Orthopaedic Association, 2010). OA varies with ethnicity, with Chinese demonstrating a lower incidence than Caucasians, and people of African descent demonstrating up to a 35% higher incidence than Caucasians (Braga et al., 2009; Nelson et al., 2010). There is a genetic component to the disease which is associated with a 30% higher risk of knee OA progression (Kerkhof et al., 2010). Two other factors which increase the risk of established OA progressing are the presence of low vitamin D (serum 25-hydroxyvitamin D) (McAlindon et al., 1996) and low vitamin C (McAlindon et al., 1996). Additionally, low selenium levels are associated with worse knee OA (Jordan et al., 2005). OA is known to progress in the anatomically malaligned knee and will accelerate in the compartment or area where compressive forces are highest (Sharma et al., 2001; Solomon et al., 2010). The risk of progression is up to four times more for medial compartment disease than for that of the lateral compartment (Cerejo et al., 2002). Ligamentous laxity is an unconfirmed risk factor for knee OA (Zhang et al., 2010), also leg length discrepancy of greater than 2cm doubles the likelihood of osteoarthritic knee symptoms and radiographic findings (Golightly et al., 2007).

Demand for TKA is expected to increase in line with an increase in the prevalence of OA (National Institute of Health, 2004). In the 10 years from September 1999 to December 2009, 333,764 knee related prosthetic procedures were performed in Australia (Australian Orthopaedic Association, 2011). Figures published by the Australian Orthopaedic Association indicate that in the 2009 calendar year there were 44,490 knee-related prosthetic procedures carried out in Australia, an increase of 7.6% on the previous year. Of these, 80.7% were primary TKA.

2.2 Pathology and presentation of osteoarthritis

Osteoarthritis is a process of progressive degenerative change with attempted repair of hyaline cartilage and subchondral bone. It is the most common joint disease in the world (Felson et al., 1998) and may be primary (i.e. no apparent cause, age related) or secondary in nature (i.e. related to other processes, e.g. diabetes, haemochromatosis, post trauma, obesity) (Kumar et al., 2005). Hyaline cartilage is present in synovial joints and coats the ends of bones. Its main functions, when combined with synovial fluid, are to reduce friction associated with joint movement and to attenuate forces associated with joint compression (Kumar et al., 2005). Hyaline cartilage is made up of Type II collagen and proteoglycans which are secreted from chondrocytes (Kumar et al., 2005). Although OA is largely thought to be a mechanical process of wear and tear, other factors such as chondrocyte viability and genetic factors may be causes. Across a broad range of ethnic groups, genome-wide association scan technology has identified three loci with alleles associated with OA, which affirm the contention that OA has a genetic component (Kerkhof et al., 2010).

Early in the disease two concurrent processes occur. The cartilage is excessively hydrated and there is a reduced density of proteoglycans; Type II collagen synthesis reduces, thereby changing the ability of the cartilage to attenuate compressive forces. Fissures form both vertically and horizontally eventually exposing subchondral bone (van den Berg, 2011). As the disease process progresses, the chondrocytes are unable to keep up with the required rate of regeneration of proteoglycans and Type II collagen thus leading to cartilage failure. In response to the load, which is now unable to be adequately attenuated by the cartilage, the cancellous bone underlying the defect becomes sclerotic and appears eburnated. The space between the articular surface narrows and small fractures and/or bony loose bodies are not uncommon. As synovial fluid enters the subchondral space through these defects, cysts are formed. Osteophytes coated with fibrocartilage present around the margins of the joint (Kumar et al., 2005; Solomon et al., 2010). The key radiographic features of an osteoarthritic joint are joint space narrowing, marginal osteophytes, subchondral sclerosis and subchondral cysts (Solomon et al., 2010).

OA was originally graded in the 1950s by Kellgren and Lawrence using x-rays (Kellgren et al., 1957). They used a five-point scale to grade OA where: 0=None, 1=Doubtful, 2=Minimal, 3=Moderate and 4=Severe. The more common contemporary method is the Osteoarthritis Research Society International (OARSI) OA cartilage histopathology assessment system (Pritzker et al., 2006). In this seven-point system, Grades 0–4 describe the articular cartilage, while Grades 5–6 describe bony changes. The grades are: Grade 0=surface intact, cartilage morphology intact; Grade 1=surface intact (superficial fibrillation); Grade 2=surface discontinuity; Grade 3=vertical fissures

(clefts); Grade 4=erosion; Grade 5=denudation (sclerotic bone); and Grade 6=deformation (bone remodelling). Figure 2-2 illustrates varying degrees of OA within a joint immediately prior to TKA.

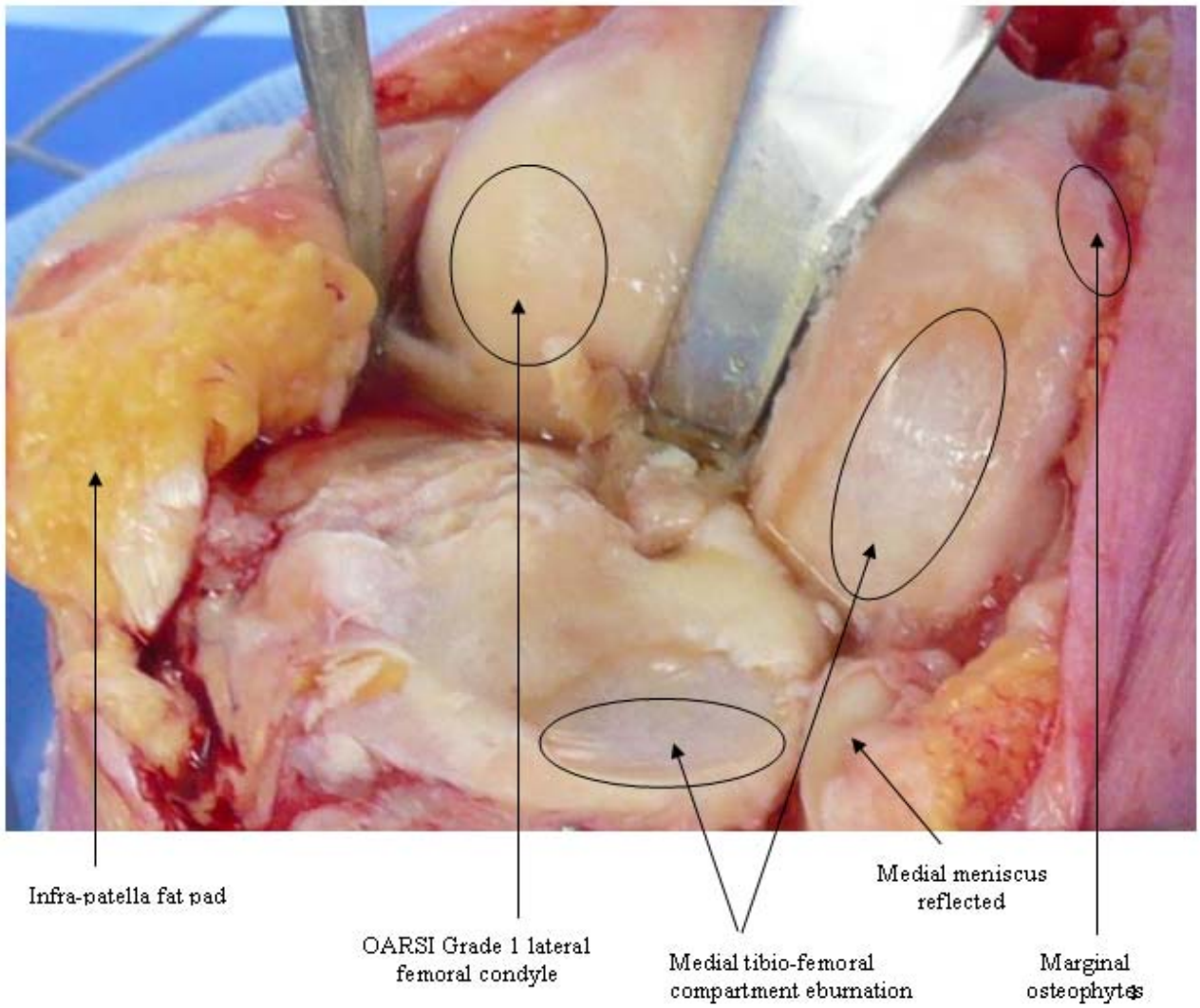

Figure 2-1 Knee joint osteoarthritis prior to total knee arthroplasty

The patient with OA of a primary nature usually presents in their fifties or beyond describing stiffness of the joint, a deep, dull ache in the joint (DeFrances et al., 2006), crepitus with movement and some loss of range of movement. The disease is progressive and debilitating. Peripheral joints most commonly effected are the knees, hips, interphalangeal joints of the fingers and both the first carpometacarpal and tarsometatarsal joints (Kumar et al., 2005). The pain associated with knee OA fluctuates, and to some degree is activity dependent. Investigation of the effects of activity modification during painful periods is difficult because patients' experience of pain and how they will answer pain-related questions is not solely dependent on the painful joint. Answers are also based on pain elsewhere in the body, its variability and the functional impact of pain (Gooberman-Hill et al., 2007).

Some areas of the knee are aneural. Types three (A delta) and four (C) nerve fibres are the primary nociceptors in the knee joint and are not found in hyaline cartilage or deep avascular portions of the meniscus (Wyke, 1981). They are found in most other surrounding structures. Importantly they are found in subchondral bone, which explains why pain near to the cartilage may be experienced (Wojtys et al., 1990). It is probable that the most pain-sensitive structures in the knee are the pre-patellar fat pad, entheses and synovium. Increased pressure in the subchondral space is the likely cause of bone pain in OA (Samuel, 1949; Kellgren et al., 1950; Dye et al., 1993).

People with OA of the knee experience lower levels of function than those without. People with knee OA are likely to have poor function if they have proprioceptive dysfunction, knee laxity, high body mass index (BMI), high pain levels, or are older (Sharma et al., 2003). Those with good knee strength, good mental health, high self-efficacy and good social supports tend to demonstrate better function (Sharma et al., 2003). More than half of people with OA are less physically active than recommended (Hootman et al., 2003). Additionally, OA sufferers' pain and disability scores are positively correlated with anxiety and depression scores (Salaffi et al., 1991). Depression is associated with a higher risk of symptomatic OA (Kim et al., 2011). Apart from reducing knee pain, TKA aims to improve function.

2.3 Knee osteoarthritis non-surgical management

A number of non-surgical options exist for the management of knee OA and may be categorised as non-pharmacological or pharmacological.

2.3.1 Non-pharmacological management

There are numerous purported interventions for the management of knee OA. Perhaps the most succinct and recent synthesis of this information is presented in the recent review by March et al., (2010) of the Australian (RACGP Osteoarthritis Working Group, 2009), United Kingdom (National Collaborating Centre for Chronic Conditions, 2008) and North American (Zhang et al., 2008) non-surgical OA management guidelines. These guidelines present evidence-based recommendations for the following non-surgical interventions for knee OA: patient information and education, weight reduction, land-based exercise, and heat and cold therapy for pain relief. There is inconclusive evidence across the guidelines regarding the value of acupuncture. Both the Australian and North American guidelines provide Level I evidence for acupuncture, whereas the United Kingdom guidelines do not recommend this modality. The use of bracing and orthoses has similar conflicting recommendations (March et al., 2010).

More recently, new evidence has emerged that Transcutaneous Electrical Nerve Stimulation (TENS) combined with either traditional Chinese acupuncture or sham acupuncture (shallow

needling at non-meridian sites) may equally reduce pain in OA knees (Suarez-Almazor et al., 2010). Interestingly, it is thought that the analgesic benefits of acupuncture are partially mediated by the acupuncturist's behaviour (Suarez-Almazor et al., 2010). When the effect of TENS or other electro-stimulation on knee OA was systematically reviewed and examined in isolation, the quality of the trials was poor and there was no evidence to support the effect of these modalities (Rutjes et al., 2009). For a population with an average BMI of 30, it was shown that 60 minutes of Tai Chi twice a week for 12 weeks could reduce pain and disability (Wang et al., 2009).

2.3.2 Pharmacological management

Pharmacological management including paracetamol, either oral or topical non-steroidal anti-inflammatory drugs (NSAIDs), topical capsaicin, opioids or intra-articular corticosteroid injections also carry consensus recommendations (March et al., 2010). NSAIDs can cause adverse events in the upper gastro-intestinal tract (ulcer, perforation, bleeding, obstruction) (Moore et al., 2006). Recent research suggests adverse events in the lower gastro-intestinal tract may have been underestimated and further research is required into the use of COX-2 selective NSAIDs versus conventional NSAIDs (Berenbaum, 2011).

Other therapies such as glucosamine, chondroitin sulphate or those included under the banner of viscosupplementation demonstrate equivocal evidence or evidence of no benefit (March et al., 2010). The effects of glucosamine and chondroitin sulphate have traditionally been examined from x-ray databases and to date, neither therapy alone or combined has reached clinically important differences in changes of joint space width. Furthermore, there is no definitive evidence that they reduce joint pain (Wandel et al., 2010).

2.4 TKA for the management of late stage knee OA

In attempts to prolong the longevity of joint integrity, other procedures for the management of knee OA such as knee arthroscopy, high tibial osteotomy (HTO) or unicompartmental knee arthroplasty (UKA) may precede an eventual TKA. Once knee OA progresses throughout the joint, however, TKA is considered to be the gold-standard in management and results of positive outcomes include relief of pain and enhanced functionality (Liang et al., 1986; Anderson et al., 1996; Ethgen et al., 2004; 2004; Kane et al., 2005; Räsänen et al., 2007; Hawker et al., 2009). Indeed, at a cost of approximately $AUD10,000 per quality of life year gained, it is a highly cost effective solution to the management of late stage knee osteoarthritis (Malik et al., 2005). Consequently, due to the resources required to perform an increasing number of TKAs and the impact of surgery on individual patients, it is important that surgical procedures are optimised to ensure efficient surgery and best possible outcomes.

2.4.1 History of knee arthroplasty

Surgical management of knee OA commenced in the late 19th century and is reported to have begun in 1861 when Fergusson created what he called a "useful limb" by resecting the articulating surfaces and creating a pseudarthrosis (Riley, 1976). The approach consisted of a wide exposure followed by debridement and re-shaping of the diseased joint tissue. Interposition of various materials (interposition arthroplasty) followed for the management of OA and was thought to have originated in 1860 when Verneuil used joint capsule between the opposing joint surfaces (Palmer et al., 2010). Reports were made in 1890 of Theophilus Gluck from Berlin implanting units made of ivory and stabilised with plaster of paris and colophony (Riley, 1976; Ranawat, 2002). Numerous other materials were interposed for the ensuing 90 years including chromicised pig's bladders (Baer, 1918), fascia lata (Putti, 1920), prepatellar bursa (Campbell, 1921), fascia lata and fat (Albee, 1928), vitallium crowns (Campbell, 1940), cellophane (Sampson, 1949), interposed sheets of nylon (Khuns, 1950), and skin (Riley, 1976). Concurrent with the era of interposition arthroplasty, arthrodesis was producing predictable and reliable outcomes, and it remained the treatment of choice during the era (Riley, 1976). Metallic interposition arthroplasty of the hip reported by Smith-Peterson in late 1930s preceded the first attempt at such a procedure in the knee by Dr Harold Boyd in 1938 (Riley, 1976). Despite further attempts at interposition arthroplasty, which persisted until 1969 (Platt et al., 1969), surgeons abandoned the technique due to poor outcomes.

Advances in metallurgy saw hinged prostheses as the theme of the next era in TKA, and it was in the 1950s that Waldius (1953) and Shiers (1954) implanted the first hinged knee prosthesis. Waldius' prosthesis was upgraded from acrylic to cobalt-chrome (Co-Cr) in 1958 and was used until the 1970s (Ranawat, 2002). Shiers did not patent his prosthesis but rather invited others to improve on his ideas. He used a lateral approach and preferred a prosthesis that allowed flexion, extension to neutral and provided medio-lateral stability (Shiers, 1954). In 1953 a distal femoral mould type prosthesis was reported by surgeons of the Massachusetts General Hospital (Jones et al., 1967). Hinged prostheses were accepted in the 1960s but the major advances came after hip arthroplasty pioneer, John Charnley, discovered that cobalt-chrome and polyethylene prostheses could be successful if cemented into bone using methylmethacrylate (Riley, 1976). Hinged prostheses did not allow for the small amounts of rotation that are required for normal knee movement and these rotational forces ultimately caused loosening of the prosthesis at the bony interface. As a solution to this, Gunston in 1968 performed the first polycentric knee arthroplasty. It was the first separate metal-on-plastic prosthesis and it retained soft tissue constraints mimicking normal knee movements. Subsequent developments saw the Freeman-Swanson cruciate-sacrificing "roller into trough" design emerge in 1970, and in 1971, the first geometric unit was used (Coventry

et al., 1972). Both polycentric and geometric units were unhinged. In the early 1970s a spherocentric, ball and socket prosthesis was the first attempt to address rotation constraints associated with cement-bone interface loosening that was experienced with its predecessors (Riley, 1976).

The next successful prosthesis was the total condylar design. Three prostheses were developed in the early 1970s by the Insall and Ranawat team in New York, USA; the Coventry and Turner team in the United Kingdom; and Townley in Michigan, USA (Insall et al., 1979; Ranawat, 2002). All of these retained the cruciate ligaments and used polymethylmethacrylate cement. The first prosthesis to sacrifice both cruciate ligaments was the Freeman-Swanson knee (Freeman et al., 1973) but this was ultimately withdrawn from the market due to tibial fixation issues associated with a short tibial peg (Ranawat, 2002). Insall and Ranawat, New York, USA, continued to develop their total condylar design with the addition of posterior stabilisation with a tibial peg (Insall et al., 1982). This peg was designed to reduce the risk of posterior dislocation and allow more flexion and better stair-climbing ability (Fu et al., 1994).

The first press-fit condylar (PFC) total knee system was implanted in 1984 by Scott and Thornhill and it retained the posterior cruciate ligament (PCL). The system was a fixed bearing prosthesis and the components could be cemented or uncemented with or without a porous coating (Scott, 2006). In 1986, the Low-Contact Stress (LCS) mobile bearing prosthesis was implanted and was the first of its kind to include a mobile bearing surface. Prostheses to this point did not have a metal tibial plate under the polyethylene. In the early 1990s the use of a metal tibial plate plus the addition of longer tibial pegs and deeper femoral boxes saw a reduction in tibial plate loosening and reduced rates of posterior subluxation (Fu et al., 1994). The PFC system was further developed in the late 1990s to eventually incorporate a mobile-bearing rotating platform that could retain, sacrifice or substitute the PCL (Scott, 2006).

Since the mid 1990s there have been many minor, but no major advances in technology, compared with earlier in the century. Some of the prosthetic designs with as yet unsubstantiated claims include gender specific prostheses, high flexion prostheses and anatomical knee prostheses (Ranawat, 2002). The latter claims to facilitate preferential spinning in the medial compartment and rolling in the lateral compartment, as happens *in vivo* in normal knees. Apart from prostheses, developments in the last 15 years have addressed fixation, bearing surfaces, kinematics, range of motion and instrumentation as well as the advent of computer assisted navigation (Ranawat, 2002). Further, the inventory available to the surgeon is substantially larger affording greater choice of components. The trend towards minimally invasive surgery (MIS) is enticing and it is being performed with regularity by more experienced surgeons. The use of regional anaesthesia and

epidural anaesthesia is also now common practice and allows patients to mobilise early post-operatively with optimal pain relief (Sarridou et al., 2008).

2.4.2 Indications for total knee arthroplasty

The only unanimously agreed indicator for TKA is a failure to relieve arthritis related pain with pharmacological and non-pharmacological therapy. There is equivocal agreement for TKA for conditions or circumstances including septic arthritis less than 12 months, nursing home residency, obesity and severe OA (Cross et al., 2006). Crockarell et al. (2003) and Solomon et al. (2010) have stated that functional deterioration due to pain, deformity (e.g. flexion contracture >20 degrees) or instability in the presence of joint pathology further indicate the need for TKA. As an additional consideration, older patients with more sedentary lifestyles may be more suitable for TKA because prostheses have a finite survivorship. Younger people with low functional levels due to deteriorating systemic arthritis might also be candidates. Current knee sepsis or a well functioning arthrodesis are contraindications for TKA (Crockarell et al., 2003; Solomon et al., 2010).

2.4.3 Indications for referring to an orthopaedic surgeon

There is little consensus on what clinical indications should be used to determine when to refer patients to an orthopaedic surgeon for surgical review (Cross et al., 2006). Indications are largely based around the failure of non-surgical management (pharmacological and non-pharmacological) to relieve pain and to improve or maintain function. These features can be variably interpreted by practitioners, and this has implications for optimising referral times. Knee pain in the presence of knee pathology that is not responsive to non-surgical management is the primary indicator for referral to an orthopaedic surgeon (Crockarell et al., 2003; Cross et al., 2006). Further indications for referral include failed joint preserving procedures such as those described above (e.g. HTO) (Cross et al., 2006). There is consensus that a major psychiatric disorder, including dementia, is a contraindication as participation in post-operative rehabilitation is required (Cross et al., 2006). Whether more objective means such as functional outcome measures can be used to determine the appropriate time to refer a patient for surgical review is unknown. This question is addressed in the research program in this thesis and is presented in Chapter 6.

2.4.4 Knee prostheses, bearing surfaces and fixation

Hinged prostheses are now used rarely in primary TKA due to the pitfalls associated with their lack of rotation. When considering the characteristics of contemporary prostheses, therefore, the bearing mechanism, stability, fixation, and prosthesis type need to be taken into account.

The bearing surface describes the articulation between the femoral and tibial component in fixed bearing prostheses and the femoral, polyethylene insert and tibial components in mobile bearing

prostheses. A mobile bearing prosthesis has an articulation between the tibial base plate and the tibial insert. Contemporary total knee prostheses are mostly mobile bearing and are commonly composed of a cobalt-chrome metal femoral component, metal tibial base plate and an ultra-high molecular weight (UHMW) polyethylene tibial insert, with or without a UHMW polyethylene patella component (Figure 2-2). Occasionally, a fixed bearing all-polyethylene tibial component or a metal tibial base plate with a fixed tibial insert may be used. Mobile bearing prostheses have an insert that can slide, rotate or slide and rotate (Jacobs et al., 2001; Gioe et al., 2009). The prostheses used in the randomised controlled trial presented in Chapter 4 were all of a rotational mobile bearing type.

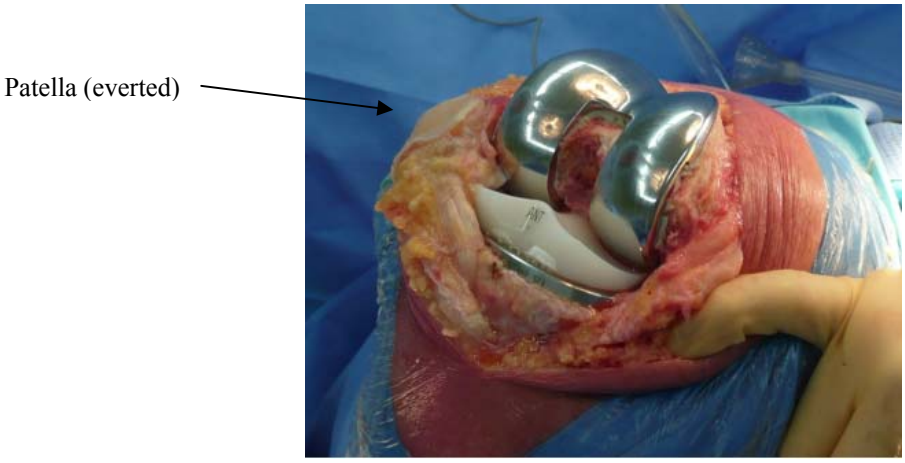

Figure 2-2 Low-Contact Stress mobile bearing prosthesis. Medial parapatellar approach.

Cobalt-Chrome metal femoral component, metal tibial base plate and an ultra-high molecular weight tibial insert.

Stability of the joint is mainly obtained through soft tissue tension and is augmented by two main prosthetic features. A flat or dished tibial articulation is considered minimally stabilised whereas a posterior stabilised prosthesis has a tibial peg and femoral box design (Insall et al., 1982). Fixation of both the femoral and tibial components of the prosthesis may be either cemented or uncemented. Hybrid fixation is the term used when only the tibial component is cemented (Rosenberg et al., 1994). Hybrid fixation of a minimally stabilised prosthesis was the protocol for the trial presented in Chapter 4.

2.4.5 Complications of TKA

Complications associated with TKA may be localised or more general in nature, and to some extent, co-morbidities and the volume of TKAs performed at a facility affect the incidence of complications. A greater rate of complication is associated with age greater than 65 years, the

number and severity of co-morbidities (e.g. ischaemic heart disease, diabetes mellitus) or if surgery is undertaken at a facility that performs less than 25 TKAs annually (Taylor et al., 1997). Mortality rates are highest in the first four days post-operatively and are higher in older, obese patients with co-morbidities (Parvizi et al., 2007). Table 2-1 outlines the major complications related to TKA (Cheung et al., 2008; Australian Orthopaedic Association, 2010; Cross, 2011).

Mobile bearing prostheses have a higher rate of revision than fixed bearing prostheses. Posterior stabilised prostheses have a higher rate of revision, especially if the patella is not resurfaced (Stiehl, 2009). Regardless of cementing technique, there is no difference in revision rates after 18 months (Australian Orthopaedic Association, 2010).

Table 2-1 Intra-operative and post-operative complications associated with TKA

Intra-operative complications
Local complications
Poor prosthesis position
Peri-prosthetic fracture (0.11 – 21.4%)
Premature cement setting
Vascular injury (popliteal artery (0.17%))
Peroneal nerve injury (associated with flexion contracture, valgus deformity, external leg compression, prolonged tourniquet (0.9 – 1.3%))
Peri-pinhole fracture during computer assisted navigated TKA
General complications
Blood loss
Anaesthetic
Cardiovascular, renal, respiratory, electrolyte
Post-operative complications
Early local complications
Deep infection (0.5 – 12%)
Deep vein thrombosis – proximal lower limb (3 – 20%)
Deep vein thrombosis – calf (23.8 – 60%)
Pain
Peroneal nerve injury (associated with post-operative haematoma)
Stiffness (associated with pain, improper technique or prosthesis size, infection, poor compliance with exercise (1.3 – 12%))
Wound complications (erythema, superficial infection, skin necrosis)
Early general complications
Pulmonary embolism (greater risk if proximal thrombi)
Post-operative atelectasis
Late local complications
Chronic pain
Patello-femoral pain
Knee instability or dislocation
Chronic regional pain syndrome
Heterotopic ossification
Stiffness (subacute infection, bonding between cement and implant, painful fibrous intra-articular bands, arthrofibrosis)
Prosthesis-related complications
• UHMW polyethylene wear, synovitis and osteolysis
• Bearing dislocation of mobile-bearing prostheses
• Cementless patellar and tibial component loosening
• Metallosis, metal hypersensitivity

UHMW = Ultra-high-molecular-weight (polyethylene)

2.4.6 Current practice in Australian total knee arthroplasty

The Australian Joint Replacement Registry is the primary reference for TKA trends in Australia. The Registry's 2011 report presents data on the 269,266 primary TKAs performed since 2003 and presents the following information(Australian Orthopaedic Association, 2011): The annual trend for total knee arthroplasty is increasing and the female population dominates the demographic, representing 57% of patients over the period 2003-2010. Most primary total knee arthroplasties have both femoral and tibial components cemented (54.8%) and approximately half involve patellar resurfacing (49.5%). The prosthetic system is usually classified by the femoral component and those most used in Australia in 2010 were the Triathlon (15.5%), PFC Sigma (11.6%), and Genesis II (10.3%), collectively accounting for 37.4% of implants. The Nexgen prosthesis has five separate models which accounted for 19.5% of all primary TKA prostheses. The 10 most used prostheses represent 83.3% of the market. The NexgenCR/Nexgen prostheses attained the best cumulative results by prosthesis as measured by the lowest cumulative revision rate for cemented total knee arthroplasty (femoral component/tibial component). The Advantim/Advantim had the best results for cementless fixation, while the Vanguard/Vanguard prosthesis was the best performer in the hybrid class (Australian Orthopaedic Association, 2011). Primary TKA performed for OA had a revision rate of 5.7% at 10 years (Australian Orthopaedic Association, 2010) with the main reasons for revision being loosening/lysis (30.7%), infection (22.2%), patellofemoral pain (13.5%), pain (9.0%) and instability (5.8%). Persons aged less than 55 years were 4.5 times more likely to require a revision than those aged over 75 years (Australian Orthopaedic Association, 2010).

The Registry does not, however, report on outcomes associated with the surgical approach that a surgeon performs. The orthopaedic unit at the hospital where the studies for this thesis were undertaken perform between 250-300 TKAs annually. Most of the surgeons routinely perform one type of surgical approach, the MPa. The systematic review presented as Chapter 3 summarises the evidence comparing the MPa and SVa. To understand how the surgical approach may affect outcomes, it is important to comprehend the anatomical structures including blood supply that are incised or otherwise insulted during the approach.

The main blood supply to the patella arises from an extra-osseous anastamotic ring of geniculate arteries and the anterior tibial recurrent artery (Scapinelli, 1967). The geniculate arteries include the descending geniculate artery (DGA), as well as the supero-medial geniculate (SMG), supero-lateral geniculate (SLG), infero-medial geniculate (IMG), and infero-lateral geniculate (ILG) arteries (Scapinelli, 1967). They supply an intra-osseous network consisting of mid-patellar and polar vessels (Scapinelli, 1967; Benson et al., 1998). An insult to the extra-osseous network will affect

the intra-osseous network. Additionally, deep peri-patellar arteries not arising from the anastamotic ring, penetrate the medial, superior and lateral borders of the patella (Bjorkstrom et al., 1980).

2.4.7 Outcome measures for total knee arthroplasty research

There are numerous outcome measures in research investigating TKA but there is no validated scale that measures objective outcome after TKA (Martimbianco et al., 2012). One of the more commonly used measures is the American Knee Society score (AKSS). It is broadly applied and consists of 100 points each for its functional and objective components (Insall et al., 1989). It contains all of the variables in Table and for this reason it was chosen as the primary outcome for research presented in this thesis.

Table 2-2 The American Knee Society score

Objective AKSS	Points
Pain	
None	50
Mild or occasional	45
Stairs only	40
Walking and stairs	30
Moderate	
Occasional	20
Continual	10
Severe	0
Range of motion	
(5° = 1 point)	25
Stability	
(maximum movement in any position)	
Anteroposterior	
<5mm	10
5-9mm	5
10mm	0
Mediolateral	
<5°	15
6° - 9°	10
10° - 14°	5
15°	0
Flexion contracture	
5° - 10°	-2
11° - 15°	-5
16° - 20°	-10
>20°	-15
Extension lag	
<10°	-5
10° - 20°	-10
>20°	-15
Objective knee score	**/100**

Functional AKSS	Points
Walking	
Unlimited	50
>10 blocks	40
5-10 blocks	30
<5 blocks	20
Housebound	10
Stairs	
Normal up & down	50
Normal up, down with rail	40
Up & down with rail	30
Up with rail, unable down	15
Unable	0
Functional deductions	
Cane	-5
Two canes	-10
Crutches or walker	-20
Other	-20
Functional knee score	**/100**

Although the score was developed by consensus opinion, it has since been found to be reliable (Objective AKSS inter-rater (ICC 0.87), intra-rater (ICC 0.80); Functional AKSS inter-rater (ICC 0.89), intra-rater (ICC 0.81) (Martimbianco et al., 2012). Further the AKSS functional score is moderately correlated with Western Ontario and McMaster Universities Arthritis Index (WOMAC) functional score (Pearsons 0.36) and shows good correlation (Pearson's linear correlation coefficient ($r>0.70$ and $p< 0.005$)) with the Short Form 36's functional capacity domain (Pearsons 0.56). Additionally it has adequate convergent construct validity with the WOMAC and is responsive for patients undergoing TKA (Lingard et al., 2001).

Oxford knee score

The Oxford Knee Score consists of 12 items; each allocated a maximum score of five points. This self-administered score reports on the following domains: pain, difficulty with washing/drying oneself, difficulty with transport, walking duration, pain on standing, limp, kneeling, night pain, interference with work, giving way shopping ability, and stair climbing (Dawson et al., 1998). The score therefore ranges from 12 (least symptoms) to 60 (worst symptoms) and is recommended as one of the most appropriate for assessment of outcome after TKA. It is reliable and sensitive to clinical change in one patient over time (Dawson et al., 1998; Davies, 2002).

3-metre Timed up-and-go test

The 3-metre timed up-and-go test (TUG) is a reliable and valid measure that quantifies functional mobility and is sensitive to clinical change over time. The patient is timed for the test in which they rise from a chair, walk three meters and return to a seated position (Podsiadlo et al., 1991).

Other outcome measures

The time post-operatively it takes for a patient to perform a straight leg raise (SLR) is an indicator of quadriceps recovery after TKA, while the length of hospital stay post-operatively is an indicator of a patients speed of recovery after a TKA. Surrogate measures for the complexity of the TKA procedure are the duration of the procedure and the surgeon's perceived level of difficulty.

2.4.8 Surgical approaches in total knee arthroplasty

There are a number of surgical approaches in TKA, the most common being the MPa, which affords excellent visualisation of the surgical field but insults the extensor mechanism 60-80mm proximal to the superior pole of the patella (Stern, 2002). The SVa and midvastus approach aim to improve on the MPa by preserving the extensor mechanism and medial blood supply (Hofmann et al., 1991;

Engh, 2002), while the less common trivector approach is a combination of the MPa and midvastus approach and purports similar benefits (Bramlett et al., 2002). The lateral approach is reserved for the valgus knee where sequential surgical releases may be required to re-align the knee (Keblish, 2002).

Surgeons select a surgical approach that they deem to be appropriate for the patient; however, there is no clinical consensus on which approach provides superior results. There is a tendency for surgeons to choose the surgical approach with which they are familiar, which is a potential problem if an alternative approach may also be appropriate, or provide better outcomes. As a background to the comparison of two surgical approaches (MPa and SVa) in this research, an outline of the salient information for surgical procedure for each of the major approaches to the knee for TKA is provided.

Medial parapatellar approach

A standard anterior midline incision is performed. The MPa extends from the medial one-third of the patella distally, 1cm medial to the tibial tuberosity, and proximally 60-80mm from the superior pole of the patella. Further dissection directly through the quadriceps allows visualisation of the quadriceps tendon, patella and patellar tendon. Most commonly, a medial reticular approach allows the patella to be everted and retracted laterally for the duration of the procedure (Insall, 1971; Stern, 2002).

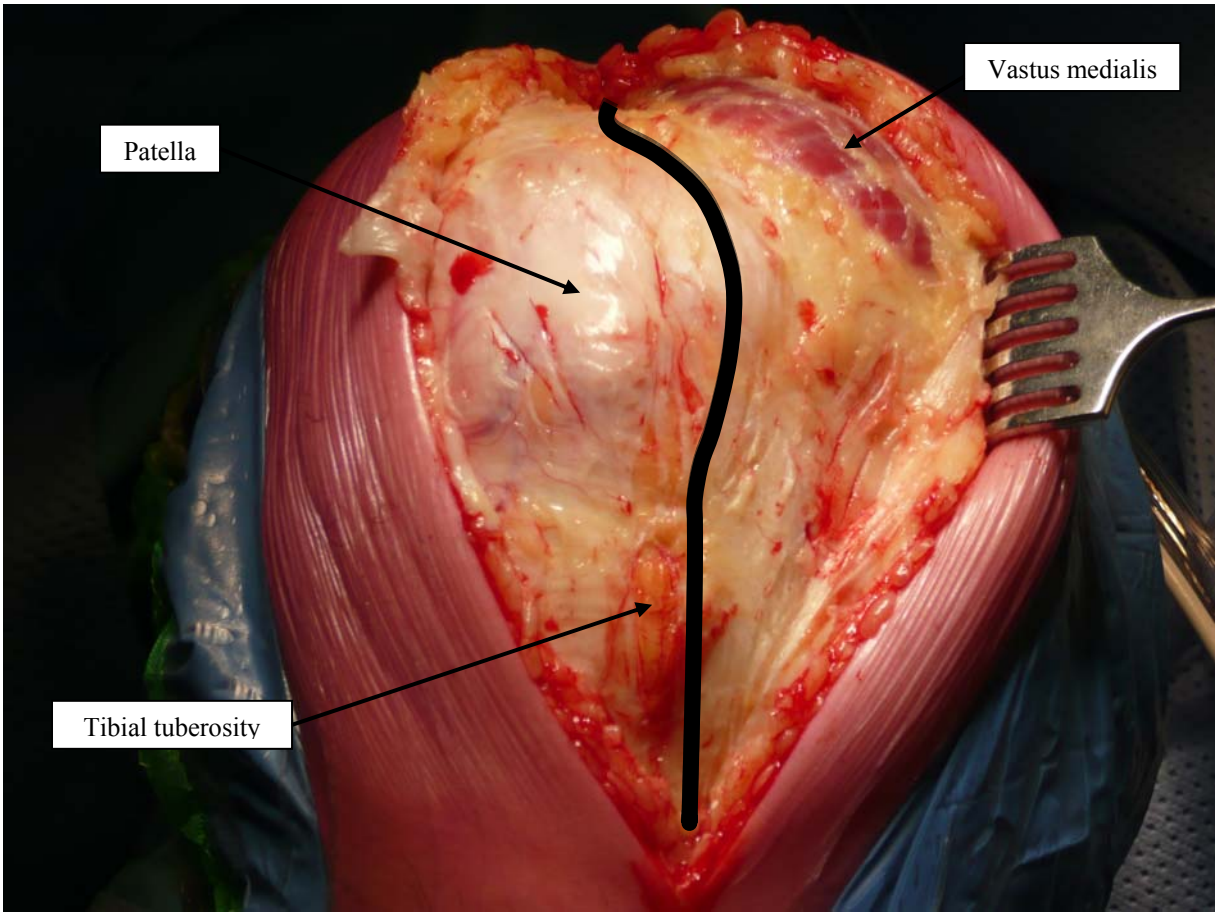

Figure 2-3 Medial parapatellar approach

Subvastus approach

A standard anterior midline incision is performed. Dissection is carried out through the superficial fascia from the quadriceps tendon distally and medial to the tibial tuberosity, incorporating a medial skin flap. The vastus medialis is elevated off the medial femur using blunt finger dissection for a distance 10cm proximal to the adductor tubercle. The descending geniculate artery is preserved within the belly of vastus medialis. The approach commences posteriorly at a mid-patellar level across the medial femoral condyle up to the medial border of the patella. It then continues distally 1cm medial to the medial border of the patella, ceasing 1cm medial to the tibial tuberosity. The patella may or may not be everted and dislocated laterally (Hofmann et al., 1991; Kharrazi et al., 2001; Vince, 2002; Cushner, 2003).

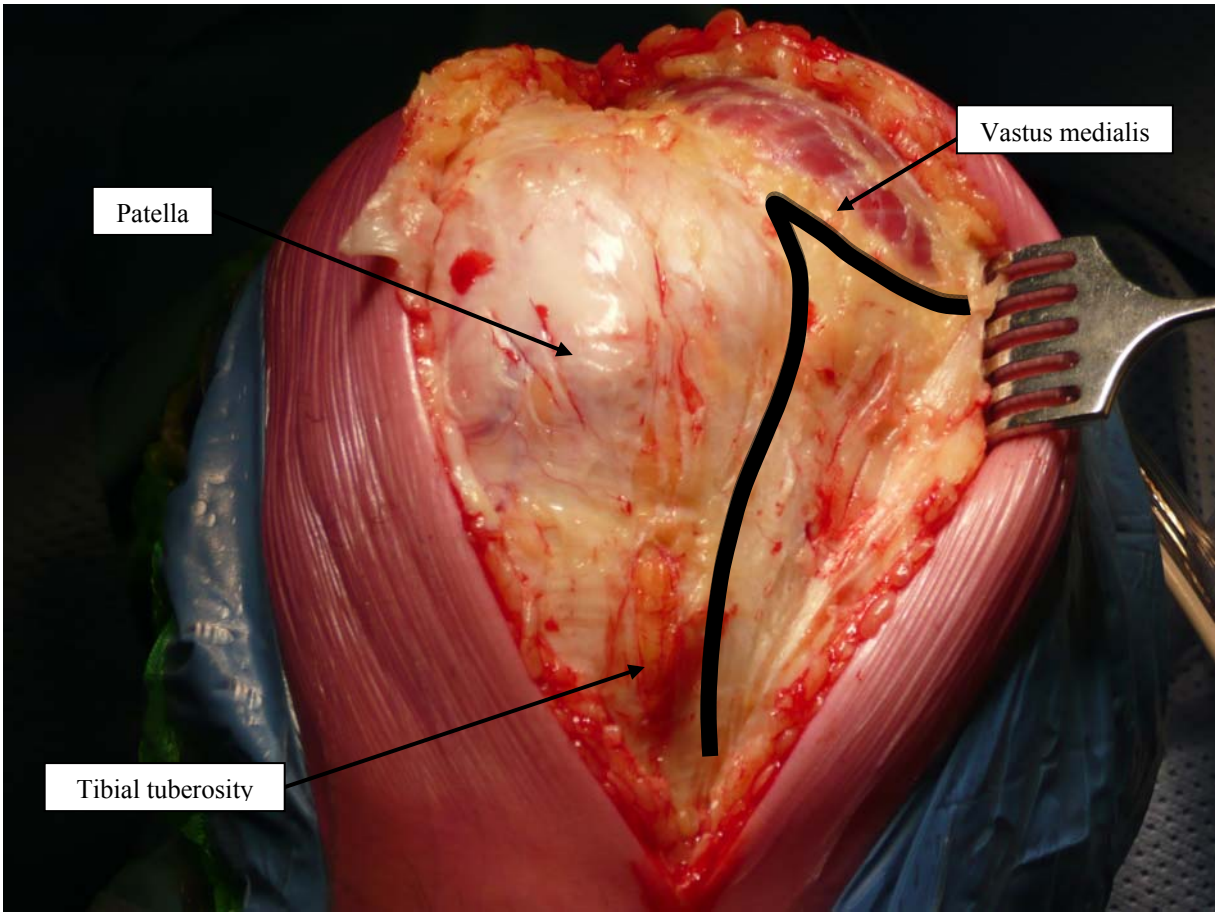

Figure 2-4 Subvastus approach

Midvastus or intervastus approach

A standard anterior midline incision is performed. With the knee in flexion the aponeurosis of the vastus medialis at the medial border of the patella is exposed. The incision is then extended distally to the tibial tuberosity. The vastus medialis insertion is exposed. With the knee flexed, a 5cm incision into the belly of vastus medialis is made, ending at the supero-medial border of the patella. The capsule is then opened from the supero-medial border of the patella, distally, releasing the insertion of vastus medialis but retaining enough capsule on the patella for repair. The capsule and synovium are then reflected laterally and medially before the most medial fibres of the patellar tendon are released prior to eversion of the patella (Engh et al., 1997; Engh et al., 1998; Engh, 2002).

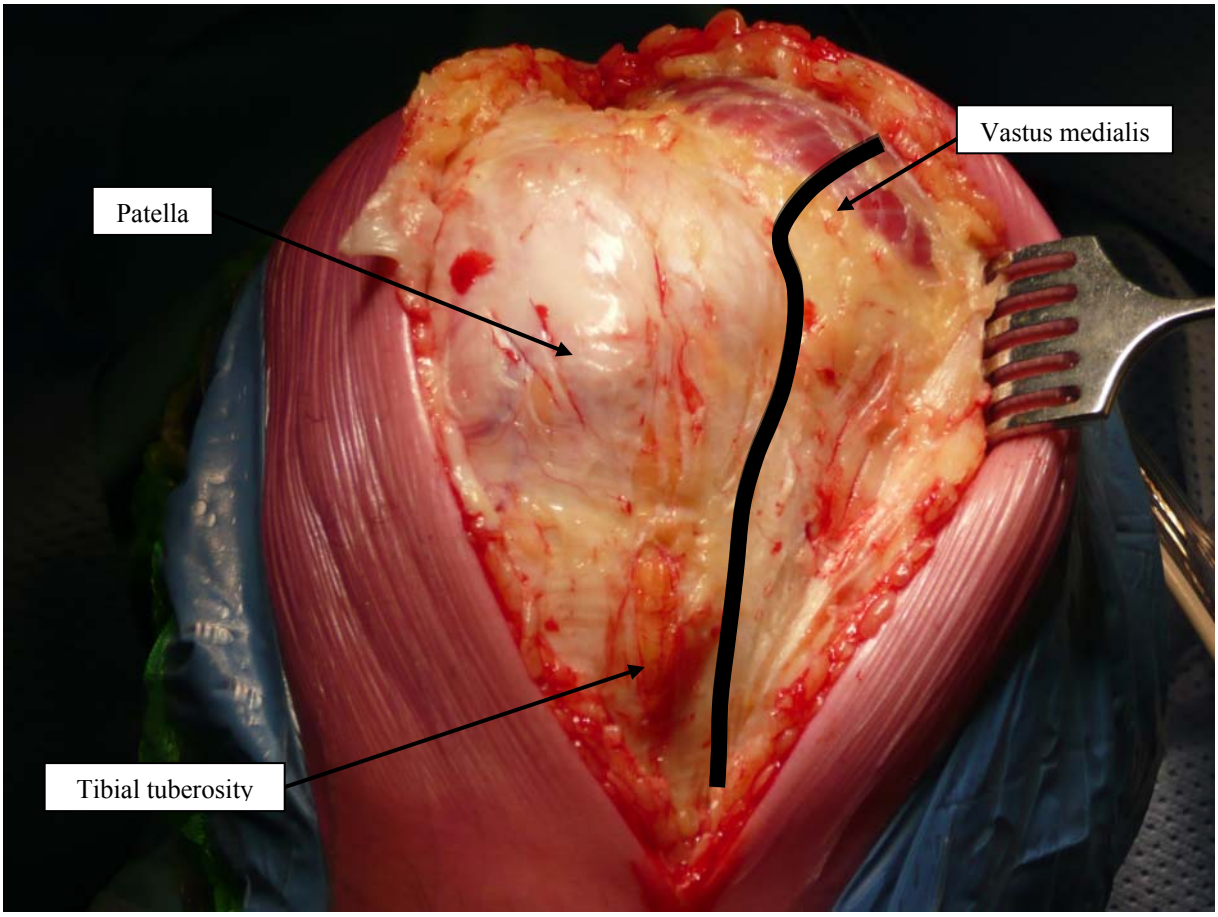

Figure 2-5 Midvastus approach

Trivector retaining approach

The trivector retaining approach is less commonly performed and purportedly retains the integrity of the vastus lateralis, vastus intermedius and vastus medialis in an attempt to minimally affect the patella during TKA. This approach is a combination of the MPa and SVa. A straight anterior midline incision is performed. The approach commences approximately 5cm proximal to the superior pole of the patella, 1.5cm medial to the insertion of vastus medialis into the quadriceps tendon. The approach extends inferior and medial to the patella to the level of the tibial tuberosity (Stern, 1994; Bramlett et al., 2002).

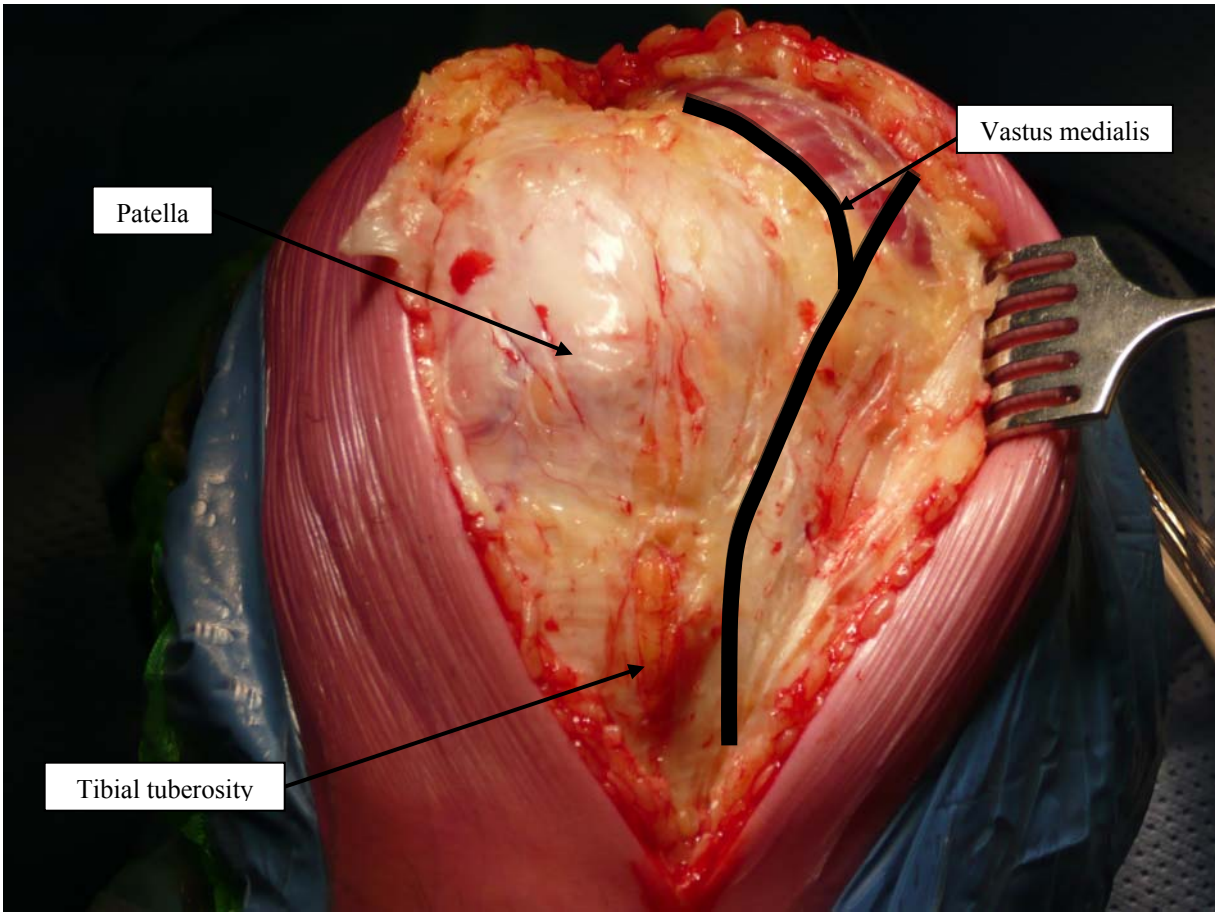

Figure 2-6 Trivector retaining approach

Lateral parapatellar approach

The lateral parapatellar approach for TKA is reserved for valgus deformity and is approached sequentially. A lateral incision is performed. The ilio-tibial band is released or lengthened, followed by a coronal plane Z-plasty. The patella is then dislocated medially followed by a tibial sleeve release and a femoral sleeve release. This approach preserves medial blood supply to the patella and leaves the medial quadriceps intact, but care needs to be taken when re-aligning the knee that traction on the peroneal nerve branches does not result in nerve damage (Keblish, 2002).

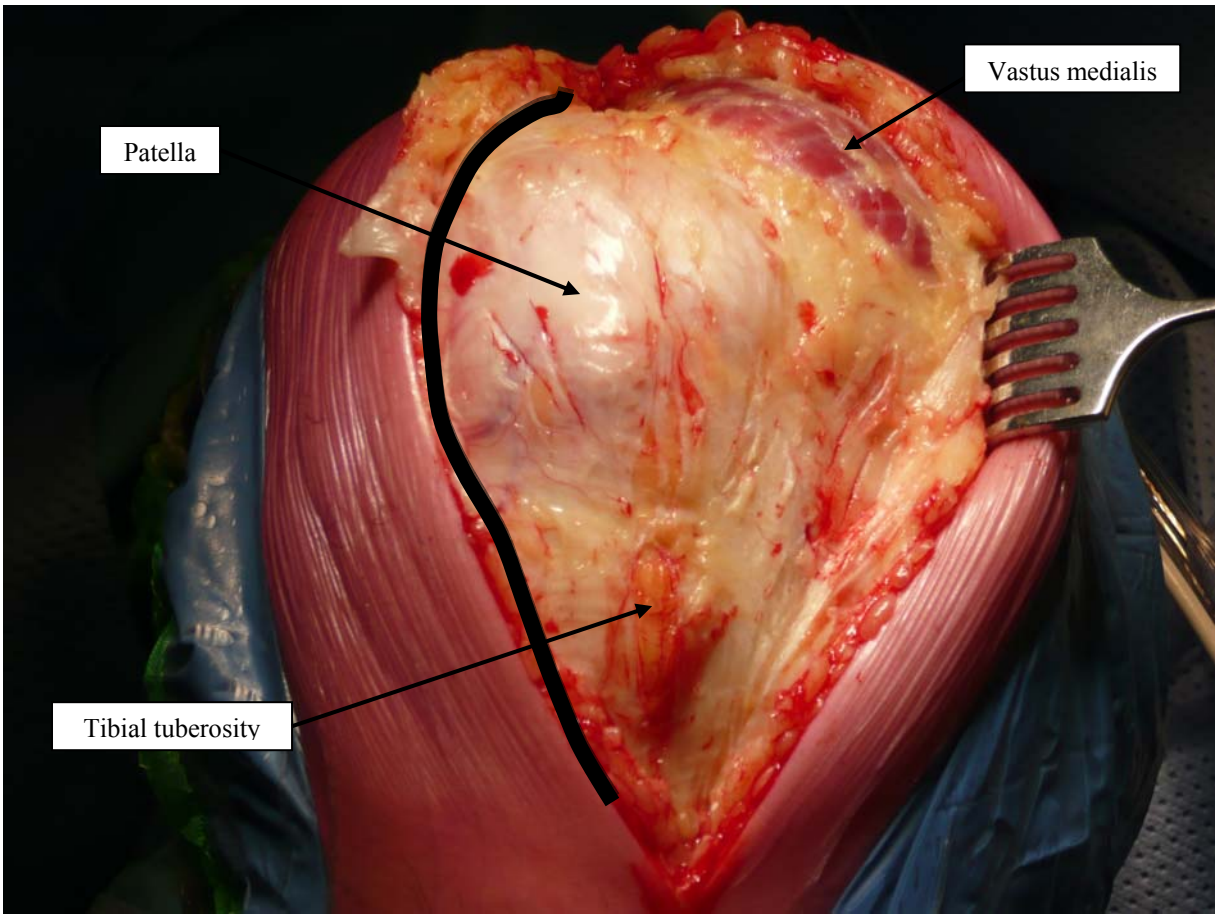

Figure 2-7 Lateral parapatellar approach

In the orthopaedic unit where the studies of this thesis were conducted, pain scores and straight leg raising ability of patients having simultaneous bilateral TKA (one surgeon performed the MPa and another the SVa) were observed to be better for the SVa. The question of superiority of either became a point of debate. The MPa is the most commonly performed approach and is reportedly preferred by over 90% of surgeons (Malik et al., 2005), but proponents of the SVa claim better outcomes. Given there is much discussion advocating better outcomes for the SVa, it is important to compare the literature (Chapter 3), conduct a trial comparing the approaches (Chapter 4), and report specifically on how patellar vascularity compares (Chapter 5). Furthermore, there is a need to

quantify indications for when patients with knee OA should be referred to orthopaedic surgeons (Chapter 6).

3 Systematic review of medial parapatellar and subvastus approaches in total knee arthroplasty

Citation:

Bourke, MG. Buttrum, PJ. FitzPatrick, PL. Dalton, PA. Jull, GA. Russell, TG. (2010). Systematic review of medial parapatellar and subvastus approaches in total knee arthroplasty. *Journal of Arthroplasty* 25(5): 728-734.

Late stage knee osteoarthritis (OA) can be successfully managed with total knee arthroplasty (TKA). Many variables affect the outcome from TKA, one of which is thought to be the surgical approach. Whilst proponents of the subvastus approach (SVa) advocate that it is less painful with an earlier return to function than the medial parapatellar approach (MPa) (Hofmann et al., 1991), it requires investigation. This chapter presents the results of a systematic review of the literature that compared the MPa and SVa in TKA.

3.1 Abstract

This systematic review was performed to compare the outcomes of the MPa and SVa for TKA. Five studies, published between 1993 and 2001 met the inclusion quality standards for the review. The methodological quality of most studies was poor, and they were not sufficiently homogenous for meta-analysis. We found that the evidence was insufficient to demonstrate a clinical or statistically significant difference between the MPa and SVa to TKA across all outcomes. Further trials with robust methodology, objective and functional outcome measures, and follow-up beyond 6 to 12 months are required.

Keywords: knee, subvastus, medial parapatellar, arthroplasty, TKA

3.2 Introduction

There were 33,737 TKAs performed in Australia in the 2005/2006 financial year. This was an increase of 5.9% compared to the previous year (Australian Orthopaedic Association, 2007), and health economists predict the number will continue to increase. Because of the resources required to service this increasing number of surgical interventions and the impact of surgery on individual patients, it is important to optimise surgical procedures to ensure efficient surgery and best possible outcomes. The purpose of this article was to perform a systematic review of the literature comparing the outcomes associated with two different surgical approaches to the knee commonly used in TKA. The two approaches reviewed were the MPa and SVa.

The MPa is arguably the most commonly performed approach and has been very successful despite disrupting the quadriceps muscle 50 to 60mm proximally from the supero-medial border of the patella. The SVa is less commonly performed and arguably more difficult for the surgeon. The SVa aims to preserve the quadriceps muscle and patellar vascularity with dissection performed deep to the vastus medialis muscle. Preservation of the quadriceps during TKA is argued to result in less pain, earlier functional recovery, and shorter length of hospital stay (Hofmann et al., 1991; Faure et al., 1993; Matsueda et al., 2000; Cameron, 2001; Roysam et al., 2001; Cila et al., 2002). Other proposed advantages of the SVa include a reduction in analgesic requirements, earlier improvement in muscle strength and earlier independent straight leg raising (Hofmann et al., 1991; Faure et al., 1993; Matsueda et al., 2000; Roysam et al., 2001). (von Langenbeck) first described the MPa for TKA in 1878. The approach provides excellent exposure and minimises tibial and femoral complications. It does, however, violate a major portion of the extensor mechanism, and the potential for vascular injury to the patella, with or without a lateral patella release, is uncommon but well described (von Langenbeck, 1878; Scuderi et al., 1987; Kayler et al., 1988; Holtby et al.,

1996). It has also been postulated that patellofemoral instability and maltracking can occur following the MPa (Matsueda et al., 2000).

In an attempt to mitigate these complications, some authors have advocated a more anatomic approach to the knee, in the form of the SVa. Although originally described in the German literature in 1929 by Erkes, Hoffman introduced the approach into the English literature in 1991 (Erkes, 1929; Hofmann et al., 1991). He claimed that the SVa preserves the integrity of the extensor mechanism and maintains the vascular supply to the patella. It preserves the vascularity of the patella by avoiding the articular branch of the descending geniculate artery that lies within the belly of the vastus medialis and joins the patella plexus with the medial superior geniculate artery at the supero-medial corner of the patella. Despite the proposed benefits of the SVa, a number of disadvantages have been reported, such as difficulty everting the patella (Matsueda et al., 2000) and more contraindications when compared with the MPa. The latter include obesity, especially combined with a short femur or a heavily muscled patient; hypertrophic changes and secondary knee stiffness or a large flexion contracture; revision total knee procedures or any previous major arthrotomy; previous high tibial osteotomy; patella infera; excessive valgus knees; skin with potential ischemic complications; extremely large tibial or femoral component size; severe osteopaenia; and rheumatoid arthritis, due to the need to place a retractor over the lateral femoral condyle for distal femoral exposure and the subsequent risk of fracture (Hofmann et al., 1991; Knezevich, 1992; Cushner, 2003; Sporer, 2006).

There are many surgeons performing both procedures on appropriate knees; however, there is no clinical consensus on which one provides superior results. There are also surgeons performing predominantly one approach where the other approach may also be appropriate. The aim of this systematic review was to evaluate current literature comparing the MPa and SVa in TKA to determine whether one has superior outcomes to the other.

3.3 Methods

A written prospective protocol defining search methods, inclusion and exclusion criteria, quality assessment, and data extraction was established in accordance with recommendations for systematic review research (Higgins et al., 2009).

3.3.1 Data Sources

The search strategy included following terms: (1) Arthroplasty, Replacement, Knee [MeSH] or “total knee and replac*” or “total knee arthroplasty” or “TKR” or “TKA”; (2) subvastus or souther; (3) media* and parapatellar*; (4) quad* and sparing; (5) standard* and approach*; (6) paramedia*; (7) #2 or #3 or #4 or #5 or #6; (8) 1 or 7. Articles published between 1950 and April 30, 2008, in all

languages were retrieved from the following electronic databases: Ovid MEDLINE (1950-), CINAHL (1982-), preCINAHL, Cochrane Central Register of Controlled Trials (CENTRAL/CCTR) (1996-), EMBASE (1966-), Scopus (1966-), Web of Knowledge (including Current Content), MetaRegister of Controlled Trials (mRCT), International Standard Randomised Controlled Trial Number Register (ISRCTN), and LILACS. No trials were identified between 1950 and 1993.

3.3.2 Study Selection

All studies comparing the outcomes of MPa versus SVa were initially retrieved. One author (MB) subsequently excluded articles (based on title and abstract) on the following criteria: (1) minimal incision surgery or computer-assisted surgery; (2) primary focus on unicompartmental knee arthroplasty; (3) primary focus was *not* SVa/southern/quadriceps sparing or MPa/standard approach; (4) cadaver procedures; (5) research protocol or article describing surgical procedures; (6) articles primarily addressing revision TKA; and (7) animal studies.

The remaining articles were de-identified by removing all references to the journal, author, year, and country of publication and distributed to three independent assessors for quality assessment and data extraction. The assessors reviewed the de-identified titles and abstracts for the following inclusion criteria: (1) the article investigated both the SVa/southern/quadriceps sparing approach and the MPa/standard approaches to TKA; (2) the article reported post-operative outcomes; (3) there was a follow-up of at least three days to ensure early post-operative outcomes were investigated; (4) the sample had at least five participants; and (5) a global knee rating scale was used such as the Hospital for Special Surgery (HSS) score or American Knee Society Score (AKSS, objective and /or functional components). Where there was ambiguity regarding the inclusion of a study in the review, MB supplied de-identified full text of the article to the assessors. If consensus between assessors could not be established a fourth reviewer was available to arbitrate; however, the fourth reviewer was not required.

3.3.3 Quality Assessment

Quality assessment was undertaken on the full de-identified text of included articles by the assessors. A quality of methodology component score (Jadad et al., 1996) out of 12 was awarded to each article based on the following criteria (score 1 or 0 per criteria) (Appendix 1):

1. Was there clear concealment of allocation?
2. Were the inclusion and exclusion criteria clearly defined?
3. Were the treatment and control groups adequately described at entry and if so were the groups well matched or appropriate covariance adjustment made?

4. Were the surgeons experienced in the various approaches prior to the trial?
5. Were the care programs other than trial options identical?
6. Were the outcome measures clearly defined in the text with a definition of ambiguous terms encountered (e.g. range of motion)?
7. Were the outcome assessors blind to assignment status?
8. Was a long-term follow-up performed? Minimum of 6 months.
9. Was the timing of outcome assessment in both groups comparable and appropriate?
10. Was loss to follow-up reported and if so were less than 5% of patients lost to follow-up?
11. Was a sample size calculation performed?
12. Did the trial include an intention-to-treat analysis?

Articles were then ranked for level of evidence on a scale of I to IV as per the Australian National Health and Medical Research Council levels of evidence scale (Appendix 2) (pilot 2005-2007).

Articles with a score of 4 or more out of 12 on the scale (Jadad et al., 1996; Clarke, 2001; Khan, 2005) and a designated level of evidence III-1 (pseudo randomised controlled trial) (National Health and Medical Research Council, 2007) or above progressed to data extraction.

3.3.4 Data Extraction

The following data were extracted independently by the three assessors. The data were then entered into a spread-sheet and checked for accuracy to enable data analysis (Appendix 3).

Number of participants in the trial

Quality of methodology component score:

1. Allocation was concealed (yes/no)
   Intervention allocation method
2. Inclusion criteria were clearly defined (yes/no)
3. Groups were matched at baseline or appropriate covariance adjustment was made (yes/no)
4. Surgeons were experienced in both approaches (yes/no)
5. Care programs other than trial options were identical (yes/no)
6. Outcome measures were clearly defined (yes/no)
7. Outcome assessors were blind to assignment status (yes/no)
8. Length of follow-up (months)
9. Timing of outcome assessment in both groups was comparable and appropriate (yes/no)
   Timing of outcome assessment
10. Percent lost to follow-up
11. Sample size calculation details

12. Intention to treat details

Other data

Type of approaches investigated

Date of trial

Location of trial

Ethnicity of participants

Sponsor of trial

Publication status

Level of evidence

Complications (numbers – not percent of total)

Deep vein thrombosis, pulmonary embolism, haemarthrosis, haematoma, infection deep, infection superficial, intra-operative damage to structures (fractures, soft tissue injury), lateral release, related to the prosthesis, respiratory, mortality, re-operation, manipulation under anaesthetic (MUA), component loosening, polythene wear, patella maltracking, subluxation, and other.

Post-operative outcomes

Pain, knee scoring system (AKSS, HSS score, Oxford knee score, other), health-related quality of life measures, length of hospital stay (days and cost [$]), days to mobilisation, discharge destination, walking aids at discharge, quadriceps function (ability to straight leg raise [SLR], lag on SLR), flexion, extension lack, blood loss, patellar vascularity, length of surgery, perceived operation difficulty reported by surgeon, imaging results, and other.

Other adverse outcomes

Other economic data.

3.4 Results

The initial search yielded 788 results: MEDLINE (160), CINAHL (20), PreCINAHL (5), Cochrane (31), Embase (193), Scopus (205), Web of Knowledge (including Current Contents) (170), mRCT (2), ICTRN (2), LILACS (0). Subsequent weekly automated searches identified no additional eligible studies.

Four hundred and three duplicate references were removed, and MB searched the remaining 385 titles for exclusion criteria. Ninety-six articles remained and were screened for inclusion criteria by the three reviewers. Thirteen articles met the inclusion criteria by the three reviewers and were included for quality assessment. Five articles were of sufficient quality (4/12 or higher, III-1 level of evidence or better). Of the remaining eight articles, the levels of evidence for seven were III-2 or

lower (level III-2 (Brodie et al., 1991), level III-3 (Bindleglass et al., 1996; Engh et al., 1996; Matsueda et al., 2000; Chang et al., 2002), level IV (Meyer et al., 1998; Ogata et al., 2004)), and one article was a reprint of an earlier version (Roysam et al., 2002). Table 3-1 presents the analysis of the studies reviewed, and Table 3-2 illustrates the data that were extracted by the three reviewers.

3.4.1 Participants and Study Characteristics

Across all trials 284 knee arthroplasties (6 unicompartmental knee arthroplasties, 147 SVa, and 137 MPa) were performed on 214 participants. The six unicompartmental knee arthroplasties were retained as the study was primarily investigating TKA, and it was desirable to include the TKAs in the same trial. Levels of evidence (National Health and Medical Research Council, 2007) ranged from level II randomised controlled trial (Roysam et al., 2001; Weinhardt et al., 2004) to level III-1 pseudo randomised controlled trial (Faure et al., 1993; Cameron, 2001; Cila et al., 2002). Randomisation method was either of the following: not stated (Weinhardt et al., 2004); conducted using sealed envelopes for consecutive participants (Roysam et al., 2001); or conducted by the senior surgeon (no method detailed) (Faure et al., 1993; Cila et al., 2002); or by hospital registration number (unclear if sequential participants) (Cameron, 2001). The average age of patients was 77 years (range, 41-88), and women (127) outnumbered men (87). Assessment time frames ranged from pre-operative, daily inpatient, to 12 months post-operatively. Four studies followed up participants at 3 months and other intervals, except for Weinhardt et al. (2004), whose follow-up was conducted during the inpatient period only. Trials were undertaken between 1990 and 2004 in the United States (Faure et al., 1993; Cameron, 2001), Turkey (Cila et al., 2002), UK (Roysam et al., 2001), and Germany (Weinhardt et al., 2004). Types of prostheses implanted varied across the studies (Appendix 4).

Table 3-1 Participants and study characteristics

Author	Participants	TKAs	Randomisation	Level of Evidence	Quality of Methodology Component Score	Follow-Up	Complications	Prosthesis
Cameron, 2001	34 (23 women, 11 men); age, 67 (41-88)	41 (16 MP, 25 SV)	Hospital number	III-1	4/12	3 wk and 3, 6, and 12 mo	Not stated	Cemented; patella resurfaced; posterior cruciate sparing
Cila, 2002	19 (18 women, 1 man); age, 66.4 (58-74)	22 (12 MP, 10 SV)	Senior surgeon decided	III-1	6/12	Pre-operative, 6 wk, and 3 and 6 mo	1 deep infection requiring revision TKA	Freeman-Samuelson TKA system
Roysam, 2001	89 (42 women, 47 men); age (MP 70.2, SV 69.8), deformity and range of motion matched	89 (43 MP, 46 SV)	Consecutive patients; sealed envelopes	II	7/12	1 and 4 wk, 3 mo	Not stated	Insall-Burnstein II (Zimmer, Warsaw, IN)
Weinhardt, 2004	52 (33 women, 19 men); age MP 73.7 ± 6.8, SV 69.7 ± 9.1	52 (26 MP, 26 SV)	Randomised but not stated how	II	5/12	Daily inpatient	Not stated	Genesis II (Smith & Nephew) with a patella inlay
Faure, 1993	20 (11 women, 9 men); age 70 (55-81)	40 bilateral (20 MP, 20 SV)	Senior surgeon decided; patient and assessor blinded	III-1	6/12	Pre-operative, 1 wk, 1 and 3 mo	1 MP haemarthrosis, 2 SV hematomas; lateral releases (5 MP, 2 SV); 2 MUAs in 1 participant; 1 patella subluxation in a valgus knee	Mixed TKA and UKA; all UKA cemented. TKA hybrid–cemented tibia, porous press fit femur

wk = week; mo = month; MP = medial parapatellar; SV = subvastus; TKA = total knee arthroplasty; UKA = unicompartmental knee arthroplasty.

Table 3-2 Extracted data

Author	Pain	Length of stay (d)	Days to Mobilisation	Quadriceps Function	Flexion (°)	Extension (°)	Blood Loss (mL)	Patella AVN	Length of Surgery/ Tourniquet (min)	Imaging Results	Knee Scoring System	Participant Preference
Cameron, 2001	*MP (day 1) 2.68/10 (1-5), SV (day 1) 5.13/10 (1-8)*	MP 4.73 (3-6), SV 4.89 (3-6)		*Days to SLR: MP 4.31 (1-8), SV 1.12 (0-3)*	MP: 84 (3/52), 101 (3/12), *103 (6/12), 105 (12/12);* SV: 91 (3/52), 106 (3/12), *111 (6/12), 114 (12/12)*		MP 684 (0-1550), SV 519 (0-2040)	No patella AVN at 12 mo	*MP 90.81 (60-120), SV 102.48 (90-125)*			
Cila, 2002			Day 1	*Cybex–6/52 60 and 180º/s peak torque MP p = .02 and .01 weaker than SV p = .09 and .05; pre-operative cf 6/52 peak torque in 60º F MP weaker but SV not p = .007*							*HSS* 3/12: MP p < .013, SV p < .017; 6/12: MP p<.01, SV p< 0.05*	
Roysam, 2001	*MP 102 mg opiate, SV 78 mg p<.001*	MP 20.7, SV 17.3		*Days to SLR: MP 12 ± 3.1, SV 8.3 ± 2.8 p<.01*	1/52: MP 55, SV 78 P < .001; at 4/52 and 3/12 no difference		MP 748, SV 527 mL *p*<.0001					
Weinhardt, 2004	Both groups improved pre-operatively: MP 6.2 ± 1.4, SV 6.3 ± 0.9 Post-operatively pain slightly lower in SV group (*p* < .01)		Day 2	*Days to SLR: MP 12 ± 3.1, SV 8.3 ± 2.8 P < .01*	*Days to passive 90º MP 11 ± 4.2, SV 7 ± 2.4 P < .01*	Days to full passive extension MP 7.7 ± 7.6, SV 2.2 ± 2.6	MP 264 ± 120, SV 243 ± 120 Peri-operative blood substitution MP 471 ± 199, SV 312 ± 215		MP 80 ± 22, SV 75 ± 6	*Correction during surgery (valgus/varus): 0º, 4 patients; 1º -5º, 1 patient; 6º -10º, 15 patients; >10º, 24 patients*; regardless of approach AP angle improved significantly *p*< .01		
Faure, 1993			Day 1 or day 2	*Quads strength (LIDO dynamometer) 1/52 and 1/12 60º/s and120º/s; better in SV* No difference between groups or to pre-operative by 3/12			MP 411, SV 375		MP 71 (tourniquet) SV 74 (tourniquet)			2 patients preferred MP, 9 patients preferred SV, 9 patients no preference' patient preference SV 4:1

Italics indicates a statistically significant difference at $p<0.05$; AVN = avascular necrosis; SLR = straight leg raise; AP = anteroposterior; MP = medial parapatellar; SV = subvastus.
*Hospital for Special Surgery score

Postsurgical complications were generally not stated. The following were recorded: one deep infection requiring revision (allocation not stated) (Cila et al., 2002), one MPa haemarthrosis, and two SVa hematomas (Faure et al., 1993). Trial sponsors were either not stated or there was no trial sponsor for any study. Intra-operative damage to structures was not reported except for Faure et al. (1993), who reported the need for one MPa and one SVa MUA in the same participant (the reason was not stated) and one patella subluxation in a valgus SVa knee 2 months post-operatively. Faure (1993) also reported additional interventions for lateral releases in five MPa and two SVa patients.

3.5 Discussion

On the basis of this review, it is not possible to draw definitive conclusions about the efficacy of the SVa compared with the MPa to TKA largely owing to the paucity of high-quality studies in the field.

Only 13 studies published between 1993 and April 30, 2008, met the initial inclusion criteria for this review. No systematic reviews or meta-analyses were found. Of the 13 studies, only five met the methodological requirements to be included. Even so, within these five studies, the Quality of Methodology Component Scores were comparatively low (range, 4-7/12), and the low evidence level (III-1) for three of the five studies reflected deficiencies in the randomisation process where allocation was decided by the senior surgeon or was not described (Table 3-1).

Although statistically significant results have been demonstrated for some outcomes in a number of the studies (Table 3-2), the results were not consistent. Neither were the studies sufficiently homogenous for meta-analysis because data were collected at different time points post-operatively and different outcome measures were used.

Outcomes were weighted toward physical rather than functional measures in all but one study (Cila et al., 2002). Therefore, the implications of the surgical approaches for patients in terms of function are difficult to ascertain. The highest quality trial (7/12) by Roysam et al. (2001) involved 89 participants with approximately equal gender distribution, and follow-up occurred at 1 week, 4 weeks, and 3 months post-operatively. The outcomes were that the SVa resulted in less pain and earlier quadriceps function compared to the MPa. The outcomes of the other four studies reviewed were not dissimilar (Faure et al., 1993; Cameron, 2001; Cila et al., 2002; Weinhardt et al., 2004). Variously, the five studies reported some statistically significant results in favour of the SVa over the MPa for the outcomes of the following: levels of pain (Cameron, 2001; Roysam et al., 2001), better quadriceps function (peak torque (Faure et al., 1993; Cila et al., 2002) and time to SLR (Cameron, 2001)), gain of knee flexion range (Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004), limitation of blood loss (Roysam et al., 2001), shorter length of surgery (Cameron,

2001), imaging results (Weinhardt et al., 2004), and better HSS scores (Cila et al., 2002) (Table 3-2). Notably, the reporting of complications was inconsistent, and a confounding factor may have been the variety within the prostheses implanted across the studies. The lower methodological quality in four of the five studies affected the ability to generalise their findings to the wider population. However, in relation to physical outcomes, the better quality studies (Roysam et al., 2001; Weinhardt et al., 2004) supported the SVa, and on balance; it appears as though less pain and better earlier quadriceps function are associated with the SVa, which is consistent with popular opinion (von Langenbeck, 1878; Scuderi et al., 1987; Kayler et al., 1988; Holtby et al., 1996).

There were no significant differences between the SVa and the MPa in patient length of hospital stay, days to mobilisation, range of extension motion, patella avascular necrosis, or participant preference. Discharge destination, walking aid at discharge, surgeon's perceived level of difficulty of approach, or a health-related quality of life measure were not stated in any study. These are important omissions because they indicate the patient's level of function. In addition, the perceived level of difficulty of the surgery may be the strongest predictor for which operative approach will be used.

There are some points to note in interpreting the findings of this review, namely, no trials of sufficient quality have been published subsequent to 2004[†]; no information on skill level of the surgeon was reported; and the studies of sufficient quality appear to predate the development of alternative approaches to TKA, such as minimally invasive surgery. Further, that one author applied inclusion criteria to titles and abstracts is considered a minor limitation of this review article.

We contend that it remains relevant to investigate the efficacy of the SVa because it is commonly performed by many experienced surgeons and trainees worldwide.

To better assess the impact of MPa or SVa on patient outcome and address the current inadequacies in the literature, further prospective double-blind, randomised, controlled trials comparing MPa to SVa in TKA are required. The trials should have the following features: adequate sample size based on a robust power calculation; pre-operative baseline measures of pain and function as well as physical knee measures; data on intra-operative factors such as tourniquet time, operation time and blood loss; inpatient and outpatient follow-up for at least six to 12 months; length of hospital stay; and surgeon's perceived level of difficulty for each approach. Furthermore, if the MPa and SVa are to be adequately compared and the results generalisable to TKA, then both approaches must be performed by multiple surgeons and a variety of prostheses need to be tested.

[†] Correct at the time of printing

3.6 Conclusion

The current evidence precludes any comment about the superiority of either the MPa or SVa to TKA. Factors such as poor study design, lack of true randomisation, and blinding affect the integrity of the currently available data. Future studies must address these methodological inadequacies, and studies with follow-up beyond 6 months with a focus on functional outcomes may better demonstrate any preference for either the SVa or MPa for TKA and patients' resulting quality of life.

4 Comparing the subvastus and medial parapatellar approaches in total knee arthroplasty: a randomised controlled trial

Citation:

Bourke, MG. Jull, GA. Buttrum, PJ. FitzPatrick, PL. Dalton, PA. Russell, TG. Comparing outcomes of medial parapatellar and subvastus approaches in total knee arthroplasty. A randomised controlled trial. *Journal of Arthroplasty* 27(3): 347-353.

It has been established that the quality of evidence investigating the relative merits of the subvastus approach (SVa) compared to the medial parapatellar approach (MPa) are poor. This chapter presents a prospective randomised controlled trial comparing the relative physical and functional outcomes between the approaches, as well as outcomes relevant to the surgeon and the organisation where the procedure is conducted.

4.1 Abstract

The MPa in total knee arthroplasty (TKA) is more common, but the SVa is less insulting to the quadriceps. Whether the SVa affords better outcomes was investigated using 90 participants with knee osteoarthritis (OA), randomised to receive either SVa or MPa and followed for 18 months. The primary outcome was the American Knee Society Score (AKSS); secondary outcomes included pain, knee range, quadriceps lag, Oxford Knee Score (OKS), 3-metre Timed Up and Go (TUG) test, days to straight leg raise (SLR), surgeon perceived difficulty, operation duration, and length of hospital stay. Analysis (n=76) revealed no significant difference in AKSS (p=0.076) or other outcomes except: AKSS Functional (AKSSFun) scores at 12 and 18 months favoured the MPa (p=0.032; p=0.028 respectively); surgeon perceived difficulty favoured the MPa (p=0.001); and days to SLR favoured SVa (p=0.044). This study found the SVa offered no clinical benefit over the MPa.

Keywords: arthroplasty, replacement, knee, medial parapatellar, subvastus

4.2 Introduction

Primary and revision TKAs performed in Australia have risen by 37.6% since 2003, and in 2008 totalled 39,283 [‡](Australian Orthopaedic Association, 2010). With health economists predicting continual increases, it is important to optimise surgical procedures to ensure efficiency and to produce the best possible outcomes.

The MPa is arguably the most common approach in TKA, despite disrupting the quadriceps muscle up to 50 to 60mm proximally from the supero-medial border of the patella. The SVa is less widely used but aims to preserve the quadriceps muscle by bluntly dissecting deep to the vastus medialis muscle (Hofmann et al., 1991). Preservation of the quadriceps during TKA is argued to result in better quadriceps function post-operatively (Faure et al., 1993; Cameron, 2001; Roysam et al., 2001; Cila et al., 2002; Weinhardt et al., 2004), less pain (Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004) and a shorter length of hospital stay (Roysam et al., 2001). Other proposed advantages of the SVa include a reduction in analgesic requirements (Roysam et al., 2001) and preservation of patellar vascularity (Kayler et al., 1988; Holtby et al., 1996; Matsueda et al., 2000). Despite the proposed benefits of the SVa, a number of surgical technical difficulties have been reported, for example, it is more difficult to visualise the surgical field and evert the patella (Matsueda et al., 2000). Factors such as obesity, muscle bulk and contractures around the knee are

[‡] Correct at the time of printing

also known to make the SVa technically difficult (Hofmann et al., 1991; Knezevich, 1992; Cushner, 2003; Sporer, 2006).

A recent systematic review highlighted the paucity of high quality studies providing evidence for the efficacy of the SVa compared to the MPa (Bourke et al., 2010). Studies to date have generally lacked the methodological rigour required to derive definitive conclusions about the outcomes of SVa or MPa. Methodological issues included poor randomisation processes where allocation was decided by the senior surgeon (Faure et al., 1993; Cila et al., 2002) and poor complication reporting (Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004), which affected the generalisability of results and contributed to the trials' relatively low quality methodology component scores (Jadad et al., 1996; Crockarell et al., 2003; Khan, 2005; Higgins et al., 2009). The highest quality trial in the review reported appropriate randomisation procedures, but their follow up extended only 3 months post-operatively (Kayler et al., 1988; Roysam et al., 2001). In one clinical trial published subsequent to this review (Bridgman et al., 2009), the SVa was found to be superior to the MPa on the outcomes of range of motion and American Knee Society Scores (AKSS) at 1 week and the Western Ontario and McMaster Universities index of osteoarthritis (WOMAC), 36-Item Short Form Health Survey (SF-36) and European quality of life questionnaire (EuroQol) scores at 1 year. This trial did not investigate immediate inpatient outcomes in the first few days post-operatively nor did it follow up beyond 12 months. Therefore further trials are required to investigate if there are any definitive benefits of the SVa compared to the MPa in the immediate post-operative phase as well as in the medium term.

To this end, a single centre, prospective randomised controlled trial was conducted in a metropolitan hospital to further compare the SVa and MPa. Outcomes were assessed pre-operatively, intra-operatively (for some outcomes), on days 1 to 3 post-surgery, and at discharge as well as at 6 weeks, 6 months, 12 months and 18 months post-surgery. It was hypothesised (i) that participants receiving the SVa would experience better early outcomes than those receiving the MPa, and (ii) that outcomes would converge by 18 months after surgery.

4.3 Methods

The study was conducted in a hospital in Brisbane, Queensland, Australia from May 2006 to November 2009. Institutional ethics committee approval was granted for this trial (Appendix 5) and written informed consent was obtained from each participant (Appendix 6). The trial was registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12606000376549) and there were no external sources of funding.

4.3.1 Participants

Eligible participants were recruited by the participating orthopaedic surgeons from patients attending their outpatient clinics and who were subsequently scheduled to undergo a TKA at the hospital. To be included, the participants were required to be aged 18 years or over, diagnosed with knee OA and scheduled to undergo primary unilateral TKA and were appropriate for either the MPa or SVa. Participants were also required to possess normal mentation[‡]; be able to attend supervised outpatient physiotherapy rehabilitation sessions over a period of 6 weeks; and be able to provide signed informed consent. Persons excluded were those: with comorbidities preventing participation in rehabilitation (e.g. severe obstructive pulmonary disease, hemiplegia following stroke); undergoing revision or bilateral TKA; having knee stiffness with less than 70 degrees of flexion or flexion contracture of greater than 20 degrees; or having undergone previous high tibial osteotomy or major arthrotomy on the operative knee (indicating inability to perform SVa as originally described) (Hofmann et al., 1991). Also excluded were persons who were unable to pre-operatively mobilise full weight bearing in a bipedal manner with or without a walking aid or who were unlikely to be able to follow the TKA clinical pathway (Appendix 7). Additionally, participants were excluded intra-operatively if they required an intervention outside the standardised surgical protocol, for example, requiring a femoral nerve block or a lateral surgical release. This enabled a better comparison of successfully completed SVa and MPa procedures.

4.3.2 Randomisation and Blinding

Randomisation was undertaken using a computer generated randomisation sequence which was created with stratification to surgeon and a 1:1 allocation using a block size of 4. Block randomisation was used to ensure an equal number of participants in each group as the trial progressed and the stratification ensured each surgeon had a similar number of participants in each surgical group. The allocation sequence was generated by a research team member (TR) who was not involved in participant contact or data collection. The allocations were placed in sequentially numbered, sealed envelopes and the envelope drawn out by a theatre nurse. Group allocation was revealed to the orthopaedic surgeon in the operating suite immediately prior to surgery.

The assessors, physiotherapists and nurses providing the post-operative care and participants were blind to the surgical procedure received by the patient. The operating surgeon was unblinded. The surgical approach and procedure was described in the original operation report, which was then placed in a sealed envelope and not opened until the conclusion of the trial. To maintain blinding of

[‡] Normal mentation was assumed to be someone of sound mind as defined by their ability to provide informed consent for surgery as determined by the treating surgeon.

the physiotherapists and nurses, a second printed temporary operation report with the surgical approach blackened on both sides was placed in the medical record following surgery.

4.3.3 Procedure

All participants who had agreed to enter the study attended a pre-operative education clinic conducted approximately 4 weeks prior to surgery. A pre-operative assessment of all baseline measures was undertaken and participants were randomised at this point.

All participating surgeons, regardless of experience with either operative approach, completed five supervised sessions with the senior consultant surgeon (JD) to standardise the SVa, which is less commonly performed than the MPa. All six surgeons performed both procedures to enhance the generalisability of the results.

Surgical procedure and post-operative care (Appendix 8)

Surgeons used their preferred prosthesis from the choice of either the Smith and Nephew Genesis II or the LCS® Depuy Mobile-Bearing total knee prosthesis. A tourniquet was fitted but only inflated for cementing of the prostheses. An identical midline skin incision was used in both procedures to ensure blinding of the other researchers in the post-operative period. For the SVa the knee was flexed for the skin incision and incision of the inferior aspect of the capsule. The vastus medialis was then dissected with the knee flexed or extended. The patella was not everted, but rather subluxed laterally. The femur and tibia were prepared and the prosthesis inserted. For the MPa, the knee was flexed and a medial parapatellar incision extending 60-70mm above the proximal pole of the patella was performed. The incision was extended inferiorly to the medial aspect of the tibial tubercle. The patella was everted for the duration of the surgery if required. As for the SVa, the femur and tibia were prepared and the prosthesis inserted. For both the MPa and SVa, wound drains exited laterally avoiding the vastus lateralis where possible and were removed on the first day after surgery. Incisions were closed with the knee in flexion of approximately 90 degrees.

Post-operative pain relief for all participants was administered via intravenous patient controlled analgesia for the first 48 hours and then subsequently by oral analgesia. Post-operative nursing care (including the use of thromboembolic deterrent stockings and removal of surgical drain) and length of hospital stay criteria were standardised for both groups. The rehabilitation of all patients was standardised according to the hospital's clinical pathway (Appendix 7) for TKA and physiotherapy guidelines for rehabilitation (Appendix 9). Following discharge, all patients attended at least two post-operative physiotherapy rehabilitation sessions prior to their 6 week review, as is conventional practice at the hospital.

4.3.4 Outcomes

The primary outcome measure was the AKSS (x/200 points) (Insall et al., 1989). For better discrimination, its component scores, the AKSS Objective (AKSSObj) (x/100 points) and AKSSFun (x/100 points) scores were also considered. Secondary outcome measures included the OKS (12-60/60 points) (Dawson et al., 1998), 3-metre TUG (seconds) (Podsiadlo et al., 1991), knee flexion and extension range of motion (ROM, degrees), quadriceps lag on SLR (degrees), days to SLR, pain (Numerical Assessment Scale [NAS, 1-10]), and knee girth (mm). These outcomes were measured at time-points 4 weeks pre-operatively (baseline), post-operatively on each of days 1-3, on discharge, 6 weeks, 6 months, 12 months, and 18 months. Intra-operative secondary outcome measures were knee flexion and extension range of movement, operation duration (minutes), surgeon's perceived level of difficulty with the operative approach (Numerical Assessment Scale [NAS, 1-10]) and tourniquet duration (minutes). Length of post-operative stay in the orthopaedic ward (days) was also recorded.

All data were collected on an electronic personal digital assistant (PDA) by physiotherapists and surgeons who were trained in its use, with the exception of the self-rated OKS which was collected as a paper-based questionnaire. Flexion, extension and quadriceps lag were measured using software on the PDA which was adapted from telerehabilitation research (Russell, 2007). This software has demonstrated criterion validity (Limits of Agreement = –1.66 to 1.76 degrees for the measurement of knee joint excursion from extension to flexion) and excellent intra-rater (ICC(2,1) = 0.97 to > 0.99) and inter-rater (ICC(2,1) = 0.93 to > 0.99) reliability.

4.3.5 Sample Size

A sample size calculation was conducted using the AKSS data from the first 22 participants from the MPa group (AKSS: 56.75 ± 14.19) and 21 participants from the SVa group (AKSS: 51.82 ± 14.04). In the absence of literature defining a minimal clinical important difference (MCID) for the AKSS, a difference of 5% was asserted to be clinically relevant for the current randomised controlled trial and the trial was powered as such. To detect a 5% improvement in the AKSS (10 points) with a two-sided 5% significance level and a power of 80%, a sample size of 32 participants per group was necessary (total n =64). Sufficient recruitment (final n=90) was undertaken to allow for a dropout rate of at least 10% over the 18-month follow-up period as well as any loss to the trial due to variations from the surgical protocol.

4.3.6 Statistical Methods

The data retained for analysis was of the participants who underwent the MPa or SVa surgical procedure as per the study protocol. All data were inspected for normality and transformed as

required prior to analysis (Appendix 10). Linear Mixed Models (LMM) were performed for analysis of continuous variables (AKSS, AKSSObj, AKSSFun, OKS, TUG, flexion, extension, quadriceps lag, pain, and girth), using surgical approach (SVa or MPa) and outcome assessment points (and their interaction effect) as fixed effects. LMM was favoured over Student's t-tests due to its ability to correctly handle correlation errors observed with repeated measures, its ability to support the random effects and hierarchical effects of the variables, and its ability to account for baseline differences (Garson, 2011). Analysis of secondary outcomes (days to SLR, operation time, tourniquet duration, surgeon rated difficulty with the procedure, length of hospital stay) was performed using one-way analysis of variance (ANOVA) to determine differences between the two treatment groups. Independent-samples Mann-Whitney U tests were used to analyse baseline demographics. A significance level of $p<0.05$ was chosen for all analyses.

4.4 Results

Ninety participants were randomized into the trial between 11 May 2006 and 18 October 2007. The follow-up of all participants ended on 12 November 2009. Figure 4-1 illustrates participant recruitment and the flow of participants throughout the study. Of the original 90 participants, 81 received the intervention and 76 were retained in the study for analysis. Nine participants, although randomised, did not receive surgery within the study period because they subsequently declined the procedure or experienced medical complications subsequent to recruitment (MPa group = 4; SVa group = 5). Five participants had unplanned interventions intra-operatively. In the MPa group, one participant received a unicompartmental knee replacement. In the SVa group, four participants variously received: simultaneous bilateral TKA; femoral nerve block; femoral nerve block and lateral release; post-operative bracing; and restricted weight bearing due to intra-operative medial collateral ligament avulsion. As these interventions/complications contravened the standardised surgical protocol, these participants were excluded from further statistical analysis. Therefore, the per protocol analysis was performed using the data from 76 participants. Within the cohort of 76, three participants were lost to follow-up, one from the MPa group at 6 months and another at 12 months and one from SVa at 6 weeks. The data of these participants was included in the analysis for the time points for which it was available.

Baseline analysis revealed no significant between group differences for gender (MPa: female 26, male 14; SVa: female 19, male 17: p=0.282) or age (MPa: 67.7±6.5; SVa: 68.1±8.2: p=0.83**)**. There were no significant differences between groups in baseline functional or clinical characteristics (Table 4-1).

Table 4-1 Baseline comparisons

Physical and functional outcome measures in the MPa and SVa groups. There was no significant between group differences for any baseline measure.

Outcome	MPa (n=40)			SVa (n=36)		
	n	Mean and Standard Deviation	Range	n	Mean and Standard Deviation	Range
Primary Outcome						
AKSS (x/200)	40	100.5±30.6	35-173	36	102.3±32.6	36-179
AKSS - Objective (x/100)	40	55.7±13.7	34-93	36	54.6±15.5	24-9
AKSS - Functional (x/100)	40	44.6±22.2	0-90	36	44.7±23.1	0-9
Secondary Outcome						
Pain (x/10)	40	4.9±2.0	1-8	36	4.9±2.1	1-7
Extension (degrees)	40	6.5±5.0	-5.7-20.0	36	7.6±5.7	0.0-20.0
Flexion (degrees)	40	117.6±12.0	88.5-140.0	36	119.0±12.5	88.5-140.0
Quadriceps Lag (degrees)	40	2.7±4.1	-5.6-13.8	36	2.4±3.5	-3.1-10.0
Girth (mm)	38	425±38	344-510	33	425±40	360-535
Oxford Knee Score (12-60/60)	30	38.6±8.6	23-53	26	38.1±8.3	25-52
TUG (3m course - seconds)	40	13.7±13.5	8.0-29.3	34	15.9±7.2	7.7-34.6

AKSS = American Knee Society Score; TUG = Timed Up and Go test

The values for the primary and secondary outcomes for the MPa and SVa groups at each follow-up time point along with results of LMM analysis for normally distributed outcomes are presented in Table 4-2. Compared to baseline values (Table 4-1), all outcomes progressively improved from 6 weeks post-operatively onwards in both the MPa and SVa groups. However, there were no statistically significant differences overall in the primary outcomes between the groups based on LMM analysis (against fixed effects of group and outcome assessment point). Post hoc analysis revealed significant differences at three specific time points. On Day one post-operatively, the SVa group demonstrated a significantly better AKSSObj score (p=0.029) (Appendix 11). However, the MPa group demonstrated significantly better AKSSFun score at 12 months (p=0.032) and 18 months (p=0.028) (Appendix 12). There was also a trend towards greater improvement in the MPa group on AKSS (p=0.076) at 18 months.

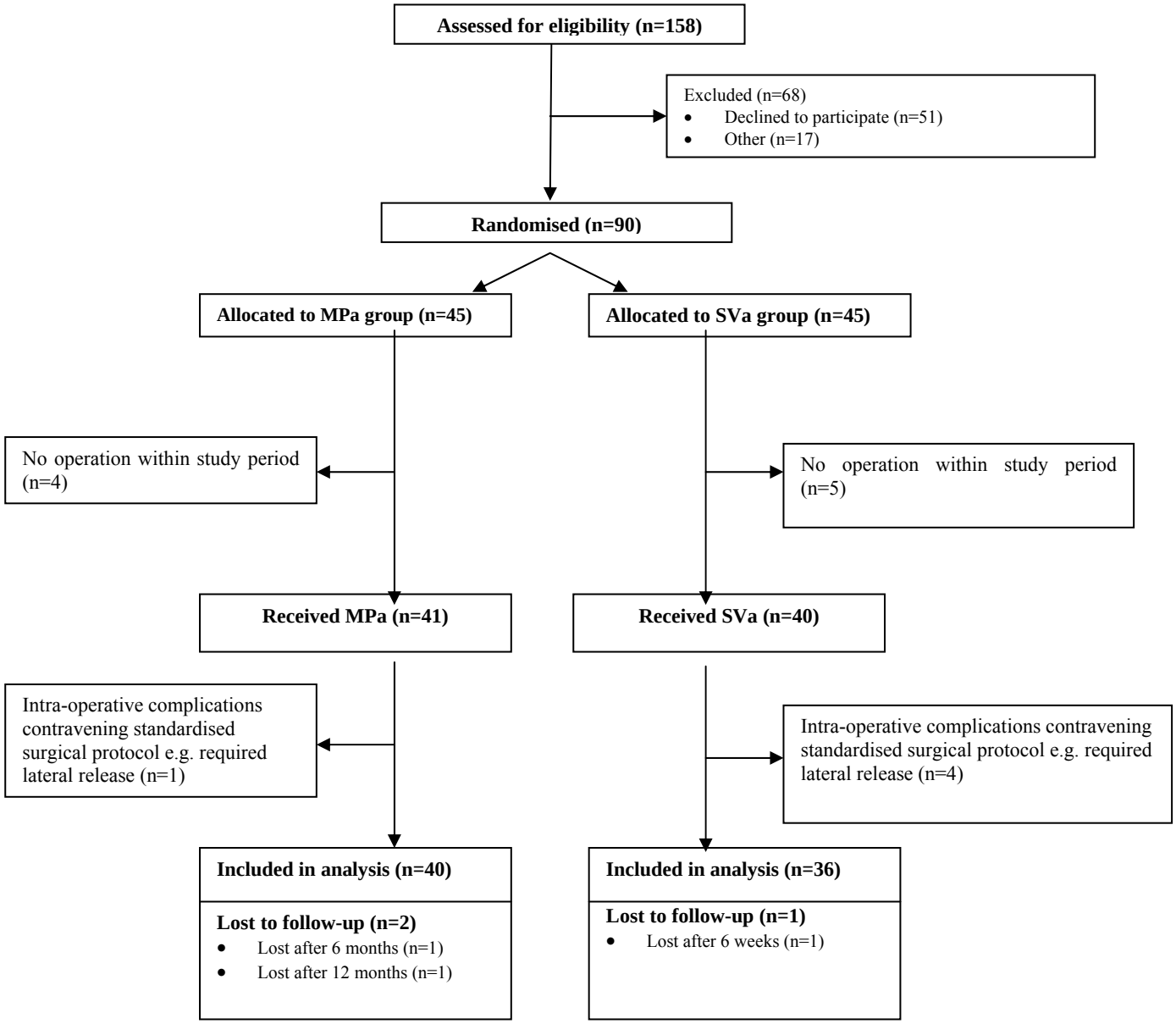

Figure 4-1 Participant Flow

Analysis of secondary outcomes revealed two significant differences only. There was a significant difference in days to SLR (MPa 2.76±1.89 versus SVa 1.92±1.59 p=0.044), indicating an earlier return of quadriceps function in the SVa group. There was a difference in surgeon perceived difficulty between surgical approaches (MPa 3.32±1.89 versus SVa 5.38±2.33: p=0.001), indicating that surgeons considered the SVa to be more technically difficult (Appendix 13). There were no differences in other secondary outcomes, including operation duration, tourniquet duration and length of hospital stay (Table 4-3), but there was a trend towards less pain in the MPa (MPa 1.66/10 versus SVa 2.63/10: p=0.097) group at 6 weeks.

Within the 18 month follow-up period there were six knee related adverse effects. In the SVa group there were two complications; aseptic loosening requiring revision and stiffness requiring manipulation under anaesthetic (MUA). In the MPa group, the four complications were aseptic loosening requiring revision, deep vein thrombosis, stiffness requiring MUA and wound breakdown requiring intravenous antibiotics.

Table 4-2 Physical and functional outcome measures

MPa and SVa groups at all follow-up points including results of linear mixed modelling (LMM) analysis for normally distributed outcomes, presented for time by allocation intervention effect.

Time	Surgical Approach	Primary outcome			Secondary outcomes						
		AKSS /200	AKSS Obj/100	AKSS Fun/100	Pain /10	Knee Ext degrees	Knee Flex degrees	Q Lag degrees	Girth (mm)	Oxford Knee Score	TUG (Transformed)
Intra-op	MPa					1.2±3.0	123.8±10.7				
	SVa					0.8±4.0	122.5±8.3				
Day 1	MPa		***50.2±16.4***		3.8±1.8	5.3±4.2	81.27±10.1	10.2±4.2	443.4±43.8		
	SVa		***59.2±15.0***		3.1±1.8	4.6±5.2	83.94±11.69	11.1±6.6	441.5±37.6		
Day 2	MPa		56.7±15.4		3.0±1.9	4.7±4.3	81.3±10.1	12.0±6.2	465.6±41.9		
	SVa		56.6±13.7		3.2±1.5	6.3±4.1	83.9±11.7	14.2±6.4	462.5±37.5		
Day 3	MPa	57.5±13.1	56.9±13.0	0.5±2.3	3.0±1.4	5.6±4.0	78.7±6.9	14.2±5.8	463.0±48.4	43.8±9.3	
	SVa	57.8±15.9	57.8±15.9	0.0±0.0*	3.1±1.7	7.4±4.8	79.5±10.4	12.8±5.1	461.6±42.0	39.1±9.4	
Discharge	MPa	53.0±13.3	50.1±10.8	2.9±5.3	2.9±1.8	6.1±3.5	84.2±9.1	11.1±5.8	463.1±45.0	38.0±8.5	0.36±0.02
	SVa	53.1±16.9	48.4±12.1	4.7±8.4	2.4±1.6	7.5±4.2	84.0±10.5	8.7±5.3	463.9±37.7	35.2±8.8	0.04±0.01
Week 6	MPa	125.9±29.2	70.2±15.7	55.7±21.0	1.7±1.3	6.8±4.6	91.1±9.7	4.3±3.9	438.1±42.6	26.7±7.0	0.10±0.03
	SVa	127.7±37.9	69.2±13.0	58.5±28.0	2.6±2.2	7.6±4.9	90.8±10.4	4.2±4.3	442.0±39.4	27.5±8.9	0.10±0.03
Month 6	MPa	151.9±28.3	80.4±12.6	71.4±20.6	1.4±1.0	3.7±5.0	108.4±12.9	3.1±4.3	427.3±40.8	21.2±8.8	0.11±0.03
	SVa	140.9±34.1	72.8±15.4	68.1±24.3	1.7±1.0	3.7±5.2	109.5±11.8	2.7±2.3	428.2±43.7	24.7±9.4	0.10±0.03
Month 12	MPa	162.7±23.0	80.9±8.8	***81.9±17.9***	1.4±0.9	3.0±4.5	116.6±13.2	1.9±3.0	422.4±41.0	19.5±6.9	0.13±0.02
	SVa	153.1±29.7	82.2±9.9	***70.9±25.7***	1.6±1.0	3.2±4.2	114.3±9.3	2.1±2.8	427.3±38.5	22.1±8.9	0.10±0.03
Month 18	MPa	167.3±27.5	84.2±14.7	***83.1±18.2***	1.8±1.8	2.7±4.2	119.6±11.8	2.0±2.5	427.5±40.8	18.8±8.9	0.11±0.02
	SVa	153.1±36.6	81.1±12.8	***72.0±27.1***	2.0±1.9	2.5±3.8	119.1±9.3	1.3±2.3	425.8±40.0	21.0±8.3	0.10±0.03
LMM		$p_{1.111;473}$=0.355	$p_{1.729;605}$=0.089	$p_{1.773;481}$=0.103	$p_{1.366;619}$=0.208	$p_{0.769;700}$=0.930	$p_{0.410;695}$=0.958	$p_{1.122;515}$=0.346	$p_{0.075;621}$=1.000	$p_{1.934;426}$=0.074	$p_{1.354;411}$=0.241

Bold italic font indicates significance $p<0.05$

*All participants scored 0/100 at this time point

AKSS = American Knee Society Score; Obj = objective; Fun = functional; MPa = medial parapatellar approach; SVa = subvastus approach.

Table 4-3 Results of analysis for interval outcome measurements

Outcome	MPa (n=40)		SVa (n=36)	
	n	Mean ± SD	n	Mean ± SD
Days to straight leg raise	37	***2.8±1.9***	36	***1.9±1.6***
Surgeon perceived difficulty (x/10)	28	***3.3±1.9 (n=28)***	26	***5.4±2.3 (n=26)***
Operation duration (minutes)	40	91.6±20.1 (n=40)	36	97.9±18.1 (n=36)
Tourniquet duration (minutes)	40	28.8±14.4 (n=29)	36	34.1±20.71 (n=31)
Length of hospital stay (days)	39[#]	4.5±1.2 (n=39)	35[#]	4.7±1.2 (n=35)

Bold italic font indicates significance $p<0.05$
[#]One participant from MPa received inpatient rehabilitation (Length of stay 37.5 days). One participant from SVa received inpatient rehabilitation (Length of stay 14.5 days). These statistical outliers were removed from analysis.
MPa = medial parapatellar approach; SVa = subvastus approach.

4.5 Discussion

The proposed clinical benefits of the SVa such as less pain, earlier quadriceps function, the potential to reduce length of hospital stay, and costs make this approach an attractive option. Although the SVa group was significantly better on Day one AKSSObj scores, at all other time points there was either no difference between the approaches, or the difference or trend favoured the MPa group. Therefore, the trial hypotheses of better early outcomes with the SVa was rejected and the convergence of SVa and MPa group outcomes at 18 months was conditionally accepted as AKSSFun scores were better in the MPa group by 12 months post-operatively. The results of this trial showed both groups made marked improvements in the primary outcomes measured over the course of the study when compared to baseline values. We are not aware of any studies which have investigated the minimum clinically important difference for the AKSS, therefore, it is difficult to rate the improvement in this study on these terms.

While the LMM did not demonstrate any difference for AKSSFun scores on the factor of group by outcome assessment point, post hoc analysis revealed a significant difference favouring the MPa at 12 and 18 months post-operatively. Inspection of the raw data revealed a generalised improvement in the MPa group which cannot be attributed to a small number of cases. Given that no significant difference at these time points was found with any other variable in the study, we are left to attribute this improvement in the AKSSFun score to the MPa surgical approach, assuming that other confounding factors that may have influenced the post-operative recovery were the same in both groups. Examples of such factors may have been the level of physical activity, medication intake, health services utilization, social support, etc.

This trial found no statistically significant differences in pain scores but did reveal a trend favouring the MPa group at 6 weeks post-operatively, similar to Bridgman et al. (2009). The results for pain did not agree with earlier studies that found less pain associated with the SVa (Faure et al., 1993; Cameron, 2001; Weinhardt et al., 2004; Bridgman et al., 2009). For example, a trial conducted by Cameron, (2001) found less pain in the SVa group at day one post-operatively, but did not state whether the patient or assessor was blinded to the approach, which may have affected the outcome.

The result of earlier SLR in the SVa group concurs with pre-existing literature describing earlier quadriceps function with the SVa (Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004). Despite this difference, earlier SLR did not result in significantly better outcomes on the AKSS or other measures (e.g. quadriceps lag on SLR, TUG), or a reduction in length of hospital stay for the SVa group in this trial. Some of the outcomes on which previous study conclusions were based (i.e. Cybex™ isokinetic dynamometer system (Cila et al., 2002) and LIDO™ isokinetic dynamometer (Faure et al., 1993)) were not performed in this trial.

Our study found no significant differences in ROM overall, or at any isolated time points, between the MPa and SVa groups. This is in contrast to earlier studies which found improved ROM with the SVa. Of these, two studies found differences favouring the SVa group at or earlier than 4 weeks. One used outcomes that we did not (days to full passive extension, days to passive 90°) (Weinhardt et al., 2004) and the other had unusually low flexion range in both groups (MPa 55° versus SVa 78° at 1 week) (Roysam et al., 2001). The third study found small but significant differences in ROM at 6 months and 12 months (Cameron, 2001). A more recent randomised controlled trial by Bridgman et al. (2009) with 231 participants, found that the SVa group had greater ROM at 1 week (7° greater increase in SVa group compared to baseline) although the scores for both groups were also relatively low (MPa 57.2° versus SVa 61.2°) compared with current results (MPa 84.2° versus SVa 84.0°, at discharge). The population demographics of Bridgman et al.'s (2009) study were similar to the present study, however, the larger sample and use of a standardised prosthesis may have contributed to their findings.

The significant difference in surgeon perceived difficulty between surgical approaches is consistent with Bridgman et al. (2009) where 'ease of exposure' scores were significantly worse in the SVa group. A surgeon's perceived difficulty with the SVa is a major reason given for undertaking the more common MPa. Even though the SVa was reported as more difficult in the current randomised controlled trial, this did not translate to a higher complication rate; in fact, there were more complications in the MPa group (n=4) than in the SVa group (n=2).The more experienced surgeons rated the SVa less difficult than did the inexperienced surgeons. Notably, despite the difference in

difficulty scores, neither the operation duration nor tourniquet duration differed significantly between the groups.

The OKS is a widely used measure in TKA research, with evidence supporting its reliability, construct validity and freedom from bias (Dawson et al., 1998; Conaghan et al., 2007). We did not find any significant differences between the MPa and SVa groups, although we feel it is probably less suited as an inpatient questionnaire and less sensitive at these time points. This relates to the seven measures pertaining to function. Five of these had usually not been attempted by participants before hospital discharge. We are only aware of one other paper investigating surgical approach in TKA which used the OKS at such an early time post-operatively but this paper did not investigate SVa outcomes (Karachalios et al., 2008).

Learning from the limitation of previous trials, great care was exercised in this study to maximise its methodological rigour. This included prospective randomisation, blinding of participants and assessors, and power analysis to determine sample size. It is possible that some findings are in contrast to existing literature because of the enhanced methodology. The quality of methodology component score described by Bourke et al. (2010) is undoubtedly higher than existing literature which ranged between 4/12 and 7/12 (Bourke et al., 2010). Although 18-month follow up is arguably short for an arthroplasty study, the primary intention of this trial was to investigate early outcomes as it was anticipated that this was where the differences would occur between the groups. Attempts were made to mitigate the influence of the type of prosthesis with a stratification process, ensuring that each surgeon had a similar number of participants in each group.

A systematic review comparing the efficacy of the SVa and MPa recommended that blood loss be collected alongside the outcomes used in this study (Bourke et al., 2010). An attempt to collect these data was made however this was not feasible due to trial resources. Future trials should include the collection of blood loss data and should also record the volume and type of pain medication.

4.6 Conclusions

This study aimed to investigate the physical and functional outcomes of the SVa compared to the MPa for TKA. We found no evidence on primary outcome (AKSS) to support the original hypothesis that the SVa affords better early outcomes when compared to the MPa. Additionally, it was evident from the randomised controlled trial that surgeons found the SVa a more technically difficult surgical approach and that the AKSSFun scores favoured the MPa group by 12 months post-operatively.

5 A comparison of patellar vascularity between the medial parapatellar and subvastus approaches in total knee arthroplasty

Citation:

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Although the results of the randomised controlled trial in Chapter 4 showed no overall difference on physical or functional outcomes between the medial parapatellar approach (MPa) and subvastus approach (MPa) in total knee arthroplasty (TKA), it did not investigate the assertions that the SVa affords better patellar vascularity and less anterior knee pain than the MPa. Vascularity was therefore examined in a subset of the population participating in the randomised controlled trial. Two novel vascularity scoring systems were developed for this study to better quantify vascularity, namely a pat:fem ratio derived from radionuclide bone imaging and a Bone Vascularity Scale (BVS).

5.1 Abstract

A complication of total knee arthroplasty (TKA) is patellar avascular necrosis (AVN). Surgical approaches for TKA include the medial parapatellar approach (MPa) and less commonly the subvastus approach (SVa). The argument that SVa retains better patellar vascularity than the MPa was investigated on 20 participants, (SVa n=10; MPa n=10) 18 months post-operatively. Outcomes were a radionuclide bone imaging technique, a new bone vascularity scale (BVS) and an anterior knee pain numerical assessment scale. Results indicated no significant difference between groups on imaging (p=0.935); the components of the BVS or anterior knee pain (p>0.999). The SVa appears to offer no benefit over the MPa in terms of patellar vascularity or anterior knee pain.

Key words: arthroplasty, replacement, knee, subvastus, medial parapatellar, avascular necrosis, CT

5.2 Introduction

With the ageing population, total knee arthroplasties (TKA) are increasing (Australian Orthopaedic Association, 2010). Clinical outcomes are usually good but 5% to 30% of poor outcomes are associated with the patella. (Hofmann et al., 1991) There is a 10-15% incidence of patellar vascular compromise in the early stages (up to seven days) after TKA (Wetzner et al., 1985; Scuderi et al., 1987) and anterior knee pain is a complication related to avascular necrosis (AVN) (Brick et al., 1989; Stoffel et al., 2007). The main patellar blood supply arises from an extra-osseous anastamotic ring of geniculate arteries, intra-tendinous circulation (Scuderi et al., 1987) and the anterior tibial recurrent artery (Scapinelli, 1967).

There are a number of surgical approaches for TKA with the medial parapatellar approach (MPa) being the most common. It divides the descending geniculate artery (DGA), supero-medial geniculate (SMG), infero-medial geniculate (IMG) (Kayler et al., 1988; Brick et al., 1989) and infero-lateral geniculate (ILG) arteries, leaving the supero-lateral geniculate (SLG) patent. Hoffman et al.(1991) (Hofmann et al., 1991) promote the subvastus approach (SVa) as an alternative procedure which results in superior vascularity of the patella when compared to the MPa by retaining the patency of both the DGA and SMG.

The literature supports a higher incidence of impaired patella vascularity in the MPa when a lateral release is performed (Scuderi et al., 1987) as a lateral release divides the SLG thus disrupting the

majority of extra-osseous and subsequent intra-osseous patellar blood supply (Wetzner et al., 1985). A study using three-phase bone scans in the very early (6-17 days) and early (2-3 months) post-operative period found that the SVa maintains better patellar vascularity (Wetzner et al., 1985). However, the literature is silent regarding the superiority of the SVa in the absence of a lateral patella release.

The aim of this study was to investigate if TKAs performed without a lateral release using the SVa maintained vascularity to the patella at 18 months, better than the MPa thereby reducing the risk of AVN and anterior knee pain. It was hypothesised that the SVa would have better outcomes for vascularity and anterior knee pain than the MPa due to the extensive dissection of the patellar arterial blood supply in the latter approach. Two methods of measurement derived from a nuclear medicine bone scan were used; (i) photon count ratio of the patella relative to the femur (pat:fem ratio) and (ii) a clinical rating scale, the bone vascularity scale (BVS) developed for this study.

5.3 Methods

This study reports the results of a secondary outcome from a larger randomised controlled trial investigating the physical and functional outcomes of the MPa and SVa (Bourke et al., 2011), as no previous research has provided empirical data on patellar vascularity from different TKA approaches. The larger randomised controlled trial was conducted from May 2006 to November 2009. Institutional ethics committee approval was granted for this trial (Appendix 14). Written informed consent for all procedures was obtained from each participant. The trial was registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12606000376549) and there were no external sources of funding.

5.3.1 Participants

The first 20 participants randomised to the MPa (n=10) and SVa (n=10) groups in the main randomised controlled trial were included in this study. The number was restricted to 20 due to financial constraints. Full details of the randomised controlled trial methodology are reported in Bourke et al. (2011). In brief, inclusion criteria were persons with knee osteoarthritis (OA) requiring a primary TKA that was to be performed at a metropolitan hospital. Participants were required to be over 18 years of age, have a diagnosis of knee OA requiring TKA that could be performed with either a SVa or a MPa, have no co-morbidities that would prevent participation in a standardised rehabilitation program that included supervised physiotherapy sessions for 6 weeks post-operatively, possessed normal mentation and could provide informed consent. Patients were

excluded if they were not expected to follow the TKA clinical pathway or were to require a lateral release or be ineligible to receive a SVa.

Participants (blinded to the surgical approach) were randomised to the MPa or SVa using a computer generated sequence. The operative and peri-operative procedures for the SVa and MPa were standardised between the five participating orthopaedic surgeons to reduce any practice effect or variation that may have affected the outcomes.

5.3.2 Surgical procedure and post-operative care

Full details of the surgical procedures, standardisation and post-operative care have been reported (Bourke et al., 2011). The MPa was undertaken as described by Stern (2002), while SVa was undertaken as described by Hoffman and Plaster et al. (1991). No patellae were resurfaced. With respect to patellar vascularity, the key difference between approaches is that the SVa preserves the DGA within vastus medialis whilst the MPa dissects the DGA and interrupts medial patellar blood flow.

5.3.3 Outcomes

Radionuclide bone imaging was chosen as the outcome measure for assessing patellar vascularity. A nuclear medicine bone scan has the ability to detect early AVN (Matin, 1983; Wetzner et al., 1985; Soucacos et al., 2004) as its method of bone uptake is proportional and sensitive to alterations in blood flow and the extraction efficiency from blood to bone (Ell et al., 2004). It is also affordable and non-invasive (Matin, 1983; Wetzner et al., 1985; Brick et al., 1989; Ell et al., 2004). After a TKA is performed the surrounding bone responds with increased osteoblastic activity. Should surgery disrupt blood supply to bone, there will be ischemic osteocyte death and a delay in healing with possible AVN within 12 months (Matin, 1983). For this reason imaging was undertaken at 18 months after each participant's surgery when any vascular insufficiency would be evident.

Eight-hundred Megabecquerels (MBq) of the radiopharmaceutical Tc99m hydroxymethane diphosphonate (HDP) was administered intravenously. Three to four hours after the injection, images for the third phase of the bone scan were taken to allow sufficient time for osteoblast absorption and retention of radionuclide in bone (Feiock et al., 2005). These images were acquired using a General Electric (GE) Infinia Hawkeye-4 camera with low energy high resolution (LEHR) collimators. A Xeleris Workstation equipped with 3D volumetrix software was used for processing and quantitative analysis of the images. Imaging parameters included a static 256 x 256 matrix, single photon emission computed tomography system (SPECT) 128 x 128 matrix and whole-body

(WB) 256 x 1024 matrix. The three dimensional SPECT/CT images were used to quantify the uptake of Tc99m HDP within the patella and femur.

Patella:Femur photon count ratio (pat:fem)

Tc99m HDP accumulates in bone in proportion to blood flow. This creates a direct relationship between the density of emitted photons measured in any region of interest (ROI) and the underlying blood flow. Photon density was measured by counting the number of photons recorded per sensor pixel within the ROI which was 10 centimetres from the distal end of the femur. However, it is well known that the metabolic activity of the patient (i.e. influenced by patient size, activity level), time of day, fasting and peripheral circulation can affect absolute photon counts. To minimise the effect of these confounding factors, a patella photon count to femur photon count ratio (pat:fem) was collected from the third phase of three phase bone scans. All femoral ROIs were healthy and without pathology. To establish the pat:fem, ROIs were drawn around the entire patella and an equally sized area on the ipsilateral distal femoral shaft, 10cm proximal to the femoral condyles; an area with relatively stable osteoblastic activity. These were standardised by noting photon counts and number of pixels per ROI, thus enabling calculation of photon counts per pixel (Ct/Px). A blinded nuclear medicine technologist calculated the Ct/Px in each ROI and expressed them as kilo counts (kcts) which reflected Tc99m HDP activity. These Ct/Px were checked for accuracy by a second blinded nuclear medicine technologist. As the nuclear medicine technologists' counts were equal, an arbitrator was not required. The ratio of patella Ct/Px to femoral reference point Ct/Px (pat:fem) was used to represent patellar vascularity with a ratio of one indicating equal vascularity of the patella and femoral ROI. A ratio of less than one indicated lower vascularity in the patella than the femur, conversely a ratio greater than one indicated higher vascularity in the patella relative to the femoral ROI. It was not possible to use the contra-lateral patella as a reference point as some participants had undergone a previous TKA on that side.

Bone Vascularity Scale (BVS)

An objective method to quantify the observation for the patella the Bone Vascularity Scale (BVS) was developed as a clinical rating scale for this study. Two blinded nuclear medicine radiologists scored patellar vascularity from SPECT/CT images for six regions of each patella giving a BVS for each region. These regions were the superior pole, inferior pole, supero-medial quadrant, supero-lateral quadrant, infero-medial quadrant and infero-lateral quadrant of the patella. A five-point scale was used to rate patellar vascularity where: 0 = Absent, 1 = Decreased (photopenic), 2 = Normal, 3 = Mildly increased and 4 = Moderately increased. Intra-rater reliability of the BVS was established using the data of nuclear medicine radiologist 1 who examined and scored the images at the time of

the scan and then again at least 12 months later. Nuclear medicine radiologist 1 was blind to the results of the first assessment when undertaking the second assessment. To establish inter-rater reliability of the BVS, a second nuclear medicine radiologist independently scored the regions of the patella on all 20 participant patellae.

Anterior knee pain

Patients with avascular necrosis of the patella usually present late with localised anterior knee pain (Soucacos et al., 2004). The Numerical Assessment Scale (NAS) for pain (Williamson et al., 2005) was used to measure the participants' subjective experience of average anterior knee pain on a scale of 1 to 10 (no pain to worst pain). This outcome was administered by an experienced physiotherapist 18 months post-operatively.

5.3.4 Statistical Analysis

All data were analysed using Stata 10, Statacorp LP (Statacorp, 2007). Intra and inter-tester reliability were calculated using quadratically weighted Kappa statistics and percent agreement was calculated. Pat:fem data and NAS anterior knee pain values were inspected for homogeneity of variance and normality and were analysed with a one-way Analysis of Variance (ANOVA). The categorical data of the BVS were analysed with a non-parametric statistic, the two-sample Wilcoxon rank-sum test. A significance level of $p<0.05$ was set for all analyses.

5.4 Results

The 10 participants in the SVa group comprised three females and seven males (mean age 69.7 years; range 56-83 years), while those in the MPa group included seven females and three males (mean age 69.8 years; range 64-86 years). All 20 participants received their allocated surgical approach and participated in the planned post-operative care and rehabilitation. There were no complications, lateral releases or other contraventions to surgical protocol or follow up in either group. The raw data for all outcomes is presented in Table 5-1.

Table 5-1 Bone Vascularity Scale (BVS) scores

(Presented by quadrant of the patella with corresponding pat:fem and anterior knee pain scores for the MPa and SVa.)

Participant number	Surgical approach	BVS rating (Possible score range 0-4)*						pat:fem	Pain x/10
		Supero-lateral quadrant	Supero-medial quadrant	Infero-lateral quadrant	Infero-medial quadrant	Sup pole	Inf pole		
1	MPa	3	2	2	2	2	2	1.50	1
2	MPa	3	2	3	1	2	2	4.33	1
3	MPa	1	2	1	1	2	2	6.10	1
4	MPa	2	2	2	2	2	2	1.12	1
5	MPa	2	2	3	2	2	2	5.30	6
6	MPa	3	3	3	3	2	2	2.33	1
7	MPa	2	2	2	2	2	2	0.96	1
8	MPa	2	2	2	2	2	2	0.80	1
9	MPa	3	1	1	3	2	2	2.07	1
10	MPa	2	2	3	2	2	2	0.93	1
11	SVa	3	3	3	3	2	2	2.01	1
12	SVa	1	2	2	2	2	2	5.24	1
13	SVa	1	3	2	3	2	2	2.00	4
14	SVa	2	3	1	2	2	2	1.65	2
15	SVa	2	2	2	2	2	2	1.07	1
16	SVa	2	1	2	2	2	2	1.01	1
17	SVa	1	1	1	3	2	2	2.27	2
18	SVa	2	2	3	2	2	2	1.77	1
19	SVa	1	2	1	1	2	2	0.98	1
20	SVa	2	3	3	2	2	2	6.64	1

*There were no scores of zero or four on the BVS. MPa = medial parapatellar approach; SVa = subvastus approach.

The pat:fem measured in this study ranged from 0.80 to 6.64. Analysis of the pat:fem revealed no significant difference between groups (MPa 2.54±1.97*;* SVa 2.46±1.92*;* p=0.935). Sample sizes were not calculated *a priori* for this study. Post hoc calculations based on the data in this study indicated that the effect size of the TKA approach on pat:fem was 0.041. Given this effect size, it was estimated that for an appropriately powered study, a sample of 18,866 participants would be required to achieve 80% power with an alpha of 0.05.

The results (Kappa, κ) for the intra- and inter-tester reliability and percent agreement for the BVS are presented in Table 5-2. They indicate very good intra-rater reliability for the BVS (κ>0.81). The results for inter-tester reliability indicate either very good (superior quadrants κ>0.81) or good (inferior quadrants κ>0.61) reliability of the BVS (Altman, 1991).

Table 5-2 Kappa values for intra- and inter-tester reliability for the BVS

	Superior pole	Inferior pole	Supero-medial quadrant	Supero-lateral quadrant	Infero-medial quadrant	Infero-lateral quadrant
Intra-rater reliability						
Quadratically weighted Kappa (95% CI)	*	*	0.853 (0.653 to 1)	0.947 (0.845 to 1)	0.853 (0.653 to 1)	0.955 (0.869 to 1)
Standard error			0.102	0.052	0.102	0.044
Percent agreement	100	100	90.0	95.0	90.0	95.0
Inter-rater reliability						
Quadratically weighted Kappa (95% CI)	*	*	0.853 (0.653 to 1)	0.824 (0.639 to 1)	0.758 (0.507 to 1)	0.792 (0.604 to 0.979)
Standard error			0.102	0.094	0.128	0.096
Percent agreement	100	100	90	85	85	80

* Unable to calculate due to insufficient variability

The BVS indicated that patellar vascularity was centred about a normal score of two for each quadrant of the patella in both the MPa and SVa groups. Both groups contained a proportion of abnormal vascularity scores (MPa 17/40 (BVS1 n=6, BVS3 n=11); SVa 21/40 (BVS1 n=10, BVS3 n=11) where 1 = decreased and 3 = mildly increased). There were no patellae where vascularity was absent (Score 0) or moderately increased (Score 4). Two-sample Wilcoxon rank-sum analysis revealed no significant difference in vascularity between the MPa and SVa groups on the five-point BVS for either pole or any quadrant of the patella (supero-lateral quadrant p=0.064; supero-medial quadrant p=0.437; infero-lateral quadrant p=0.573; infero-medial quadrant p=0.490; superior pole; inferior pole (not calculated due to insufficient variability).

The anterior knee pain NAS scores were likewise no different between groups (MPa **1**.5±1.6*;* SVa 1.5±0.97; p>0.999). Only one of the 10 participants (10%) receiving the MPa reported pain (see case 5, Table 5-1; NAS 6/10) whereas three of 10 participants (30%) receiving the SVa reported pain though of lesser rated intensity (see cases 13, 14, 17 Table 5-1; two scores of 2/10 and one of 4/10).

5.5 Discussion

This study found no significant difference between the SVa and MPa for the outcomes of patellar vascularity assessed using radionuclide bone imaging and the clinical BVS. There was also no

between group difference in the mean rating of anterior knee pain at 18 months post-operatively. The hypothesis that the SVa would afford better results for vascularity and anterior knee pain than the MPa due to the extensive dissection of the patellar arterial blood supply in the latter approach was rejected.

Previous literature has suggested a link between anterior knee pain and avascular necrosis of the patella (Holtby et al., 1996; Soucacos et al., 2004). In this study we failed to see a strong link. Of the 20 participants, 20% (4 of 20) experienced anterior knee pain (Table 1). This is consistent with existing literature which reports pain rates from 5-30% (Hofmann et al., 1991). Each of these four cases demonstrated some changes in vascularity on the BVS, with three participants showing decreased vascularity in at least one quadrant, and indeed one with increased vascularity in one quadrant. However, 12 participants (60%) without anterior knee pain also demonstrated some changes in vascularity on the BVS bringing the total percentage of participants with vascularity changes to 80%. Notably, there were no avascular patellae (BVS = 0), and perhaps severe localised anterior knee pain is only present once AVN is well established. There are many factors other than AVN that may contribute to anterior knee pain in patellae that are not resurfaced, including osteoarthritis and patellar mal-tracking. Therefore, given that there was no difference between groups on either vascularity measure it was not surprising that no difference in anterior knee pain rates was found between the groups. With so few cases of anterior knee pain in this study, it is not possible to further explore the relationship between pat:fem ratio, BVS vascularity measures and anterior knee pain. Future studies with a specific focus on exploring this relationship should include a larger number of cases with anterior knee pain.

Angiography as a direct method for measuring patellar vascularity was not used in this study due to cost and risks associated with femoral artery cannulation, contrast reactions and the higher dose of radiation relative to radionuclide bone imaging. Thus radionuclide bone imaging was used to indirectly measure the arterial perfusion of the underlying bone. It is clear that absolute photon counts per sensor pixel are of little value given the numerous variables that can affect radiotracer uptake (e.g. metabolic rate). We therefore used a ratio of counts in the patella compared to a normal area of bone to address this problem. It is not possible at this point to state what confidence intervals for the pat:fem ratio constitute “normal” until this method is validated against a gold standard such as angiography. However, for the purposes of this study, it was possible to compare ratio data between groups to infer that if blood flow was compromised in one compared to the other group.

As an adjunct to the pat:fem ratio, the BVS was developed to enhance and rate subjective reporting of vascularity status. The scale demonstrated good intra and inter-rater reliability for practitioner

ratings of vascularity on SPECT/CT scans. The fact that the results produced by the BVS are consistent with previous findings (Wetzner et al., 1985; Scuderi et al., 1987) is encouraging and when combined with the high level of inter and intra-rater reliability, the BVS may present as a useful outcome measure for evaluating patella vascularity. The mildly increased vascularity in 26% of cases was an unexpected finding and to the authors' knowledge there is no literature that reports increased vascularity in the patella as late as 18 months post-operatively. One potential explanation may be residual increased osteoblastic activity or OA of the patella (Stern, 2002), in which case, scans at a later interval may be appropriate.

As the clinical meaning of relative pat:fem ratios is unknown, there was some concern when the magnitude of these ratios was compared visually to the clinical BVS rating of vascularity. For example, on occasions where high BVS scores were used to describe increased vascularity in the patella (see case 11, Table 1) a relatively low pat:fem ratio of 2.01 was observed. This is in contrast to occasions where low BVS scores, indicating a reduction in patella vascularity (see case 3, Table 1) were coupled with higher a pat:fem ratio of 6.10. In support of future investigation of the utility of the pat:fem ratio as a quantitative measure derived from radionuclide bone imaging, it is possible that the occasional and mild degrees of patellar avascularity observed overall in the study sample meant that pat:fem ratios were clustered within a potentially normal range. It is notable that the clinical rating scale (BVS) and the pat:fem ratio were concordant on their findings of no between groups differences in patellar vascularity.

A major concern is the very low statistical power associated to the pat:fem ratio. Further investigation of the reliability and validity of both the BVS and the pat:fem ratio must be undertaken with larger sample sizes (to increase statistical power) to establish their utility as robust outcome measures for patella vascularity.

The lack of difference in vascularity or anterior knee pain between groups in this study may have been influenced by the exclusion of participants requiring a lateral release. While this was a necessary criterion for the larger RCT, it is probable that by excluding this procedure from this study the SLG was retained in both groups. Consequently, blood supply to the patella may have been retained through the SLG, and as reported by Kayler et al. (1988) (Kayler et al., 1988), this may be sufficient to retain patella vascularity hence there was no difference between groups on vascularity or anterior knee pain. This is in spite of the fact that the DGA and SMG would be augmenting the supply in the SVa group. Future studies should include a broader TKA sample including those who require lateral release procedures as this will enable a more accurate examination of the effect the SLG has on retaining patellar vascularity. No *a priori* sample size calculation was performed for this study, therefore, results cannot be generalised to a broader TKA

population. However, data from the participants in this study suggests that 18,866 participants would be required in a future study for it to be adequately powered to detect a difference between the groups. Studies of this magnitude are improbable and therefore future research is unlikely to reach a different conclusion.

Although the results of this study are not definitive, no difference was detected and they provide preliminary evidence for no difference between the SVa and MPa on the outcomes of patellar vascularity and anterior knee pain.

6 Towards a model that determines when a patient with knee osteoarthritis should be referred for specialist attention: a case control study

The baseline measures of the patients recruited for the randomised controlled trial presented the opportunity to undertake novel research. This research investigated an indication for when to refer a patient with knee osteoarthritis (OA) to an orthopaedic surgeon for assessment of their suitability for total knee arthroplasty (TKA). This chapter presents work that is building towards a method to assist primary health practitioners to quantify the circumstances when referral to an orthopaedic surgeon is warranted (without consideration of surgical approach).

6.1 Background

Demand for TKA is expected to increase in line with an increase in the prevalence of knee OA (National Institute of Health, 2004). The role of TKA as an effective treatment for patients with end stage OA of the knee is well established (Callahan et al., 1994, 1995; Dieppe et al., 1999). Figures published by the Australian Orthopaedic Association indicate that in the 2009 calendar year there were 40,675 knee related prosthetic procedures carried out in Australia. This was an increase of 3% on the 2008 calendar year. Of these, 80% were primary TKA. In the nine years from September 1999 to December 2008, 289,274 knee related prosthetic procedures were performed (Australian Orthopaedic Association, 2010).

In Australia, patients requiring TKA are referred to an orthopaedic surgeon by a primary health care provider (e.g. general medical practitioners). By this stage, patients have often exhausted conservative management for OA including non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy and intra-articular corticosteroid injections (Cross et al., 2006). There are various opinions on when to refer for TKA amongst orthopaedic surgeons, rheumatologists and primary health care providers (Dieppe et al., 1999; Australian Orthopaedic Association, 2010). Pain (Mancuso et al., 1996; Naylor et al., 1996; Hadorn et al., 1997), loss of joint space or joint damage (Mancuso et al., 1996; Hadorn et al., 1997), high patient motivation (Mancuso et al., 1996), functional impairment (Naylor et al., 1996; Hadorn et al., 1997), radiographic severity (Kellgren et al., 1957; Ahlback, 1968), and problems with care giving (Naylor et al., 1996; Hadorn et al., 1997) have all been cited as potential indicators. However, there are currently no definitive quantitative criteria to assist primary health care providers in determining when patients warrant referral to an

orthopaedic surgeon for consideration for surgical intervention. This may result in either inappropriately early or delayed referral.

There are a large number of patient-assessed scoring instruments for knee joint disorders (Garratt et al., 2004) as well as a number of clinical rating systems for TKA (Davies, 2002). To date these instruments have been used predominantly to measure TKA outcomes (Anouchi et al., 1996; Mizner et al., 2005; Lim et al., 2006) and, to the authors' knowledge, have not been assessed for their use in guiding referral for TKA. The conduct of the randomised controlled trial with its attendant outcome measures provided data and an opportunity to preliminarily investigate these measures to inform suitability of patient referral to surgical consultation.

The aim of this study was to conduct modelling to determine if physical measures, patient-assessed scoring instruments and/or clinical rating systems could be indicators for the timely referral of patients to an orthopaedic surgeon for surgical consideration.

6.2 Methods

Ethical approval was provided by the relevant tertiary institutional and hospital medical ethics committees (Appendix 15) and all participants provided written informed consent (Appendix 16). A case control study was undertaken in the process for a randomised controlled trial (Trial registration ACTRN12606000376549/2009).

6.2.1 Participants

Fifty participants per group were recruited. The TKA group comprised 50 patients from a hospital outpatient orthopaedic clinic who were invited to participate in the randomised controlled trial after they were assessed by an orthopaedic surgeon as being appropriate for TKA surgery with the following inclusion criteria. They were required to be at least 18 years of age, have a primary diagnosis of OA, be suitable for either a MPa or SVa and have normal mentation. Participants for the control group (n = 50) were recruited over a one month period through local advertising, and were age and gender matched as closely as possible to the TKA group. Control group participants were required to have no knee pain with daily activities, no history of knee pathology or surgery and have normal mentation. Participants in both groups were excluded if they had concomitant medical conditions that would prevent them from performing the required assessments, were unable to mobilise bipedally with or without the use of a walking aid or were unable to provide informed consent. Recruitment of control participants was limited due to financial restrictions.

6.2.2 Outcomes

Measures of the following independent variables were collected.

1. American Knee Society Score (AKSS x/200)(Insall et al., 1989). The AKSS is a simple, concise, health practitioner rated system incorporating functional and objective measures of knee function (Insall et al., 1989; Davies, 2002). Each of the AKSS subscales is scored on a 100 point scale where higher scores reflect better performance. The objective knee score (AKSSObj x/100) awards points for parameters of pain, stability, strength, alignment and range of motion. The functional score (AKSSFun x/100) awards points for walking distance and stair-climbing, but deducts points for the use of walking aids.
2. Three-metre Timed Up and Go (TUG, seconds) test (Podsiadlo et al., 1991). The TUG is a self-paced timed test of functional mobility. The reliability and validity of the TUG in the elderly population has been demonstrated (Podsiadlo et al., 1991). Participants are timed from when they rise from a standard armchair, walk three metres, turn and return to the original sitting position.
3. Passive knee flexion and extension range of movement (degrees).
4. Quadriceps lag on straight leg raise (SLR, degrees). This was used as an indicator of quadriceps strength, defined as the difference between knee joint angle when the knee was passively extended and when an active SLR was performed to a degree where the heel was no longer in contact with the bed.

Data pertaining to the questionnaire and physical tests were collected on electronic personal digital assistants (PDA) by physiotherapists trained in their use. Knee flexion and extension range of movement and quadriceps lag were measured using software on the PDA which was adapted from telerehabilitation research (Russell, 2007), as noted in Chapter 4, Section 4.3.4 – Outcomes.

6.2.3 Statistical Methods

Statistical analysis was conducted using STATA Version 10.0 (Statacorp, Texas, USA) (Statacorp, 2007). Univariate logistic regression models were fitted for each variable (with TKA/control group as the dependent variable) to determine their predictive ability. Participants with outlying scores (>3 standard deviations from the mean) for any variable were excluded from further analysis, along with their matched control in order to maintain a balanced design.

At the modelling stage, multivariate logistic regression models were constructed from the most strongly predictive variables (based on the univariate analyses). Other variables were added systematically and Wald tests were used to examine the significance of each variable included in the model. If a term was not shown to be significant ($p<0.05$), it was removed and an alternative term was entered. The best fitting models were compared based on their ability to accurately predict the TKA outcome (predictive probability ≥ 0.50) for each patient, and the interpretability of the odds ratios. Intuitive judgement was used in the model building process. For example, when odds

ratios were tending to infinity or zero, this was considered implausible. Similar judgement was used when comparing models during sensitivity analysis, where each range of motion parameter was systematically varied by 1° and 5°. Thus when odds ratios were considered implausible, a model was deemed to be less clinically applicable.

6.3 Results

Data were collected for the TKA group prior to surgery at a mean of 52.5 +/- 7.5days. Cases (n=2) and controls (n=6) with outlying data for any outcome were excluded from further statistical analysis. Thus the analysis was conducted on 84 participants, 42 in each group, with six different surgeons performing variable numbers of procedures. Sample characteristics and outcomes of these participants are displayed in Table 6-1.

Table 6-1 Sample characteristics and variables.

	Group	
	TKA	**Control**
No. of participants	42	42
Age (years ± SD)	68.2 ± 6.8	67.7 ± 6.4
Gender (male; female)	18; 24	18; 24
Flexion (degrees) (mean ± SD)	117.77 ± 12.40	140.42 ± 7.77
Extension (degrees) (mean ± SD)	7.67 ± 3.82	0.74 ± 2.78
Lag (degrees) (mean ± SD)	2.34 ± 2.71	1.34 ± 1.25
AKSSObj median (range)	54 (35 – 82)	91 (78 – 100)
AKSSFun median (range)	50 (0 – 90)	100 (70 – 100)
TUG (seconds) (mean ± SD)	13.55 ± 3.43	7.26 ± 1.46

AKSS = American Knee Society Score; Obj = objective; Fun = functional; TUG = Timed Up and Go test.

Control group participants were selected if they had no knee pain with daily activities and if the AKSSObj featured pain in 50/100 points, then only the AKSSFun was retained in the analysis. Univariate logistic regression modelling was undertaken on five variables (flexion, extension, lag, AKSSFun and TUG). The four strongest predictors of probability (p<0.001) used as 'bases' for the model-building process were extension, flexion, AKSSFun and TUG. Lag (p=0.366) was not used as a base for model building, but was included as a subsequent term (Appendix 17).

Two models were identified which predicted TKA with plausible odds ratios for each variable and with greater than 95% accuracy.

6.3.1 Model 1

Statistical analysis found Model 1 to be:

$$Prob_{(TKA)} = e^{[16.440 + -0.266*AKSSFun + 0.770*Ext]}/(1 + (e^{[16.440 + -0.266*AKSSFun + 0.770*Ext]}))$$

It was based on AKSSFun/extension components and correctly predicted whether patients required TKA in 82 out of 84 instances (2.4% failure rate) (Table 6-2).

Table 6-2 AKSSFun/extension probability model (Model 1) and characteristics.

Model variables	Odds ratio	95% CI	*p* value	Model accuracy	
				TKA group	Control group
Extension (degrees)	2.16	1.13 - 4.12	0.02	41/42 (97%)	41/42 (97%)
AKSSFun	0.77	0.60 - 0.98	0.03		

AKSS = American Knee Society Score; Fun = functional.

6.3.2 Model 2

Statistical analysis found Model 2 to be:

$$Prob_{(TKA)} = e^{[43.591 + -0.143*AKSSFun + -0.245*Flex]}/(1 + (e^{[43.591 + -0.143*AKSSFun + -0.245*Flex]}))$$

It was based on AKSSFun/flexion components and correctly predicted whether patients required TKA in 81 out of 84 instances (3.6% failure rate) (Table 6-3).

Table 6-3 AKSSFun/flexion probability model (Model 2) and characteristics.

Model variables	Odds ratio	95% CI	*p* value	Model accuracy	
				TKA group	Control group
Flexion (degrees)	0.78	0.62 – 0.99	0.04	40/42 (95%)	41/42 (97%)
AKSSFun	0.87	0.79 – 0.95	<0.001		

AKSS = American Knee Society Score; Fun = functional.

To evaluate the sensitivity of the two models, the extension parameter was systematically varied by 1° and 5° for model 1, and the flexion parameter by 1° and 5° for model 2, while maintaining a constant AKSSFun score. The odds ratio for Model 1 was found to be 2.16 and 47.06 for 1º and 5º parameter changes in extension, respectively. The change in Model 2 was more clinically plausible with an odds ratio of 1.28 and 3.40 for 1º and 5º parameter changes in flexion, respectively.

Although neither model demonstrated complete accuracy in prediction, failure to predict the correct outcome was most frequently observed in atypical presentations. For example, one control group participant scored poorly on the AKSSFun (80 points) and demonstrated considerable loss of extension range of motion (7.4º) compared with other control participants. Their predictive probability was calculated as 0.70 and, as this was above 0.50, they were considered to have been assigned to the TKA group. The details of five participants who were incorrectly assigned and their respective predictive probabilities are displayed in Table 6-4.

Table 6-4 Probability model testing: Incorrect predictions for five participants.

Model	Participants	Group Membership	AKSSFun (points)	Extension (degrees)	Flexion (degrees)	Probability (of TKA)[#]	Predicted group
Model 1 AKSSFun/ extension	1	Control	80	7.39		0.70	TKA
	2	TKA	80	3.48		0.10	Control
Model 2 AKSSFun/ flexion	3	Control	70		130.93	0.82	TKA
	4	TKA	90		134.51	0.10	Control
	5	TKA	90		135.00	0.09	Control

[#] Probabilities >0.50 were assigned to the TKA group.
AKSS = American Knee Society Score; Fun = functional.

Two additional models were obtained which predicted TKA with equivalent or slightly better accuracy than Models 1 and 2. These were the extension/AKSSFun/TUG and extension/AKSSFun/Lag Models. However, the additional terms (TUG and Lag) did not achieve significance in the model, based on the Wald test and odds ratio confidence intervals and were therefore removed. Furthermore, as they did not achieve significance, the extra time it would take to clinically obtain the third variable was deemed unjustified.

6.4 Discussion

Two statistical models, based on physical measures of knee movement and clinical rating systems, were found to accurately predict the correct group membership to either TKA or control, for participants in the study. These models can be administered rapidly as they incorporate indicators of knee disease and dysfunction that are routinely assessed in clinical settings. The use of such models may provide primary health care practitioners with an objective, quantifiable method of determining when patients warrant referral to an orthopaedic surgeon for consideration for TKA. The AKSSFun/flexion model may be administered in a clinical setting using the website www.uq.edu.au/tru/tkrprob (Appendix 18)

It was not surprising that the functional component of the AKSS (stair climbing ability, walking distance and walking aid use) was retained in both models as pre-operative function is frequently reported as a predictor for TKA and TKA outcome (Fortin et al., 1999; Jones et al., 2003; Desmeules et al., 2009). Patients awaiting TKA have poor function and quality of life (Desmeules et al., 2009) which is likely to be reflected in this outcome measure. The opposite is also true; participants with no or mild knee pathology will perform to a higher level on this outcome measure. For this reason a higher score on the AKSSFun appears to be a protective factor, reducing the likelihood of a TKA allocation, in both models.

Both proposed models also incorporate a measurement of knee range of motion, either extension or flexion. Again, this was not surprising as loss of knee range of motion is a common element of the osteoarthritic disease process (Tanzer et al., 1989) and a factor which is significantly improved with TKA intervention (Aderinto et al., 2005). As expected, both the presence of an extension lack (or fixed flexion deformity) and a loss of flexion were factors linked with the need for TKA. A sensitivity analysis, whereby the flexion and extension parameters were systematically varied by 1 degree and 5 degrees respectively, while maintaining a constant AKSSFun, assisted in determining which model was the most sensitive to change while maintaining predictive ability and plausible odds ratios. The odds ratio for Model 1 was found to increase to 47.06 for a 5 degree change in extension. It was considered less plausible that a 5 degree change in extension would be associated with an odds ratio as high as 47 (Model 1), therefore it appears that Model 2, that is, AKSSFun/flexion, demonstrates the greatest clinical applicability.

Using the model presented in this paper, a primary health care provider such as a general medical practitioner or physiotherapist may gain an indication of when they should refer a patient with knee OA to an orthopaedic surgeon. The model is not presented as a definitive guide for patient referral, but could contribute to decision making. Ultimately, the surgeon will consider a multitude of factors such as knee pain, diagnostic imaging, joint deformity and functional impairment and other psychosocial factors when determining suitability for TKA.

A number of limitations were identified in this work which affects the applicability of the results. The potential for selection bias with respect to selection of TKA cases is acknowledged, although this was at least partially mitigated by the involvement of six different surgeons in the selection process. The use of volunteers for the control group, rather than a random sample of the population, may have also introduced an element of volunteer bias (Bland, 2000). The TKA group (n=52) were participants in a larger randomised trial currently being undertaken by the authors. Therefore the outcomes explored in this research were limited to those of the existing trial. Additionally, the modelling process was only conducted on outcomes that demonstrated a normal distribution, and participants with outlying data (>3 SD) were excluded from further statistical analysis. This meant that six participants from the control group were excluded: one with a TUG of 16.0 seconds, one with loss of extension of 9.9° and four with a lag (6.7°, 7.3°, 8.5° and 11.5°). Two participants from the TKA case group were also excluded: one with a TUG of 29.7 seconds and one with loss of extension of 23.3°. The ability of the models to accommodate such extreme values is unknown.

Another limitation is that the sample used for testing the predictive ability of the models was the same as that which was used to generate the model, thus limiting the generalisability of the results. Given the potential value of the quantifiable elements of the model, future studies are warranted to

investigate the ability of the model to accurately predict the need for referral to surgeons in patients with varying (very mild to severe) levels of OA. Prospective testing on a larger sample size, including patients with a full spectrum of knee pathologies, should be undertaken to determine the accuracy of these models in the clinical setting. The modelling of additional variables such as the Western Ontario and McMaster Universities Index of Osteoarthritis (WOMAC), Medical Outcomes Study (MOS), 36-Item Short Form Health Survey (SF-36) and the European quality of life questionnaire (EuroQol) may result in alternative models and should be included in future studies.

It is important to emphasise that the model is not absolute and is not designed to reduce the decision to a simple mathematical formula. It is presented as a way to interpret multiple, and sometimes incongruous, (e.g. poor knee flexion but can ascend/descend stairs normally) outcomes succinctly. The model attempts to synthesise commonly measured outcomes which can then be used in the decision making process surrounding referral to an orthopaedic surgeon.

6.5 Conclusion

A model has been identified that includes the AKSSFun component and knee flexion range of motion (AKSSFun/flexion). In limited testing, it accurately predicted the probability of undergoing TKA in over 95% of the sample in this study. This model shows promise to be used as an adjunct to conventional indicators by clinicians who are deliberating when to refer a patient with knee OA to an orthopaedic surgeon for a surgical consultation. Further research is required to addresses the limitations outlined for the current model.

7 Discussion

Total knee arthroplasty (TKA) is an effective surgical procedure for the management of end stage knee osteoarthritis (OA). In the context of an ageing population and increasing incidence of knee OA, the frequency of TKA is increasing and, based on the Australian TKA joint registry data, the trend is expected to continue (Australian Orthopaedic Association, 2010). It is important to optimise surgical outcomes and minimise both the impact on individual patients and the limited resources in health care systems. The author is a senior physiotherapist in orthopaedics in a metropolitan hospital. The interest in outcomes of TKA with different surgical approaches was initiated by the clinical observations of earlier straight leg raise (SLR) ability observed following the subvastus approach (SVa) in patients having simultaneous bilateral TKA (one SVa and one medial parapatellar approach (MPa)) and seemingly faster return of function in this knee during the patients' hospital stay. It followed that perhaps these findings may translate to earlier function, shorter length of hospital stay and consequent reduction in health care expenditure. This anecdotal observation was biologically plausible and was consistent with proponents of the SVa in TKA who have historically claimed earlier quadriceps function and less pain associated with this approach over the MPa (von Langenbeck, 1878; Scuderi et al., 1987; Kayler et al., 1988; Holtby et al., 1996). However, a search of the literature revealed little evidence to support this clinical observation which prompted the research program presented in this thesis. This chapter presents the important findings of the research, discusses the implications and limitations of findings and outlines future research directions.

7.1 Systematic review of MPa and SVa in TKA

A systematic review of the literature was undertaken in order to gain a greater understanding of the effects of surgical approach in TKA. This review was the first published review in the field to compare the outcomes of the MPa and SVa in TKA. An in-depth analysis of five papers included in the review revealed promising results in favour of the SVa. Of the papers that reported the results of a knee scoring system (Cila et al., 2002; Weinhardt et al., 2004) or quadriceps function (Faure et al., 1993; Cameron, 2001; Roysam et al., 2001; Cila et al., 2002; Weinhardt et al., 2004), all were in support of better outcomes in the SVa group. As outlined in Chapter 3, some studies found favourable outcomes at different time-points in the SVa group on the outcomes of pain (two out of three), knee flexion (one out of two), blood loss (one out of four), and tourniquet duration / length

of surgery (one out of three) (Table 3-2). While these results seemed to support the efficacy of the SVa, the methodological quality of most studies was poor, as they either failed to randomise appropriately, adequately conceal allocation, report complications, define inclusion and exclusion criteria, or define outcomes. In addition, the use of heterogeneous outcomes prevented pooling of data for meta-analysis which may have revealed stronger conclusions. The papers investigating length of hospital stay (Cameron, 2001; Roysam et al., 2001) and patellar avascular necrosis (Cameron, 2001) found no difference between the groups. That one author applied inclusion criteria to titles and abstracts is considered a minor limitation of this review article.

Following the publication of the systematic review, Bridgeman et al. (2009), published a high quality manuscript which revealed a favourable result for the SVa over the MPa 12 months post-operatively on the American Knee Society Score (AKSS). This paper addressed many of the limitations of previous trials that compared the two approaches, however, it did not report on days to straight leg raise (SLR) which is commonly used as an indicator of early quadriceps function (Cameron, 2001; Weinhardt et al., 2004). The authors acknowledged these limitations and concluded that there was "some evidence" that patients with a SVa have better outcomes than those with a MPa at one week and one year following surgery. Given the evidence to date, there was insufficient or equivocal evidence upon which to claim the SVa affords better outcomes than the MPa.

7.2 Comparing the SVa and MPa in TKA: a randomised controlled trial

In order to address deficiencies identified in the existing literature, a randomised controlled trial was designed with robust methodology, industry standard physical and functional outcome measures, and follow-up to 18 months post-operatively. To facilitate the validity and transparency of the trial, it was designed, conducted and reported according to the principles of the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher et al., 2001).

Physical and functional outcomes were collected pre-operatively and at 10 time-points which extended to 18 months post-operatively. The primary outcome was the AKSS (Insall et al., 1989), which is knee specific and incorporates physical (pain, range of motion, stability, alignment, lag on SLR, extension lack) and functional (walking distance, stair climbing ability, walking aid) measures proportionately, and is commonly used in TKA trials (Gioe et al., 2009; Juosponis et al., 2009; Bonutti et al., 2010). The Oxford Knee Score (OKS) (Dawson et al., 1998) was collected pre-operatively and from day three onwards. It is reliable, valid and widely used in TKA research (Conaghan et al., 2007). The inclusion of these two outcomes addressed a deficit in knee specific

scoring systems which were absent from four of the five papers in the systematic review (Faure et al., 1993; Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004) (see Table 3-2).

The Three Metre Timed Up and Go (TUG) test (Podsiadlo et al., 1991), a valid and reliable measure of functional mobility, was included to augment the AKSS Functional (AKSSFun) score as were the separate measures of knee flexion and extension range of motion, quadriceps lag on SLR, and pain. Days to SLR was the preferred indicator used to compare the approaches on the outcome of early quadriceps function, as this is a benefit commonly given to the SVa. It is also a better indicator of quadriceps function than days to mobilisation which is often reported, as the latter can be impacted by a multitude of other factors including surgeon protocol, pain and nausea. Knee girth measurement was chosen as the simplest and most cost-effective quantifiable method of comparing swelling of the knee. Additionally, to compare efficiencies of the approaches and to be consistent with existing literature, length of post-operative stay (Cameron, 2001; Roysam et al., 2001) and operation duration (Faure et al., 1993; Cameron, 2001; Weinhardt et al., 2004) were recorded. Rather than use the latter as a surrogate measure for difficulty with the procedure, a rating of surgeon perceived level of difficulty with the operative approach was collected as a direct measure of difficulty. Tourniquet time was also recorded in the event that local thrombo-embolic complications needed to be investigated. Eighteen months follow up was ideal for this study because it afforded time for pain to subside, function to improve and outcomes to potentially converge (Faure et al., 1993; Keating et al., 1999; Berth et al., 2007; Juosponis et al., 2009).

The robust methodological design of this randomised controlled trial included randomisation of allocation, concealment of allocation with blinded assessors and participants, and sample size calculation. Linear mixed modelling conducted for the analysis of continuous variables revealed no difference on any outcome at any time-point between the groups except for earlier SLR (mean difference – on average 0.9 days earlier, p=0.044) in the SVa group, which is similar to previous research (Cameron, 2001; Weinhardt et al., 2004). Consistent with this finding was a significantly better AKSS objective (AKSSObj) score in the SVa group on day one post-operatively (mean difference nine points, p=0.029). While it was expected that results in both groups would converge at latter time-points, this was not the case and the MPa scored better on AKSSFun at 12 and 18 months.

7.2.1 Straight leg raise earlier in the SVa group

Earlier quadriceps function in the SVa group, as demonstrated by time to SLR (mean difference on average 0.9 days earlier, p=0.044), was apparent during inpatient hospital stay. This finding concurs with previous research (Cameron, 2001; Roysam et al., 2001; Weinhardt et al., 2004) and anecdotal clinical observations on patients having simultaneous bilateral TKA; one SVa and one MPa.

Despite this result, length of hospital stay, which might be expected to be less in a patient whose quadriceps are functioning earlier, was no different between the groups. Sixty percent of patients who mobilised on the first post-operative day, regardless of approach, could perform a SLR which indicates that it is not a requirement in order to mobilise. All participants, however, had control of SLR prior to discharge, per the trial protocol. This highlights the limited impact of this isolated observation in terms of clinical or financial advantage.

7.2.2 AKSSObj – Favours SVa group day one post-operatively

Significantly better results on the AKSSObj score favouring the SVa group (mean difference nine points, p=0.029) were observed on the first day post-operatively. Exploration of the raw data suggested that the reason AKSSObj was better on day one was because more participants in the SVa group were able to perform a SLR (63.8%; 23/36) compared to the MPa group (37.5%; 15/40). While it may be tempting to accept the trial hypothesis H1(i): *That participants receiving the SVa would experience better early outcomes than those receiving the MPa* based on these results, the group difference did not persist beyond the first day post-operatively, which is very early in terms of arthroplasty time frames. Therefore, it was not deemed that the SLR and AKSSObj isolated findings constituted support for H1(i). Other trials have reported on earlier quadriceps function with the SVa up to three days post-operatively (Cameron, 2001; Weinhardt et al., 2004), but these findings were not confirmed in the current trial.

7.2.3 AKSSFun – Favours MPa group 12 months and 18 months post-operatively

AKSSFun scores were found to be higher in the MPa group from 12 months onwards (12 months: mean difference 11 points, p=0.032; and 18 months: mean difference 11.1, p=0.028). Interestingly, this finding is incongruous with two trials reported in the systematic review which suggested that the SVa is superior at 12 months (Cameron, 2001; Cila et al., 2002). In the absence of literature defining a minimal clinical important difference (MCID) for the AKSS, a difference of 5% was asserted to be clinically relevant for the current randomised controlled trial and the trial was powered as such. The difference in favour of the MPa group on the AKSSFun outcome was approximately 10% indicating a statistically better and seemingly clinically relevant result for the MPa group on this outcome. Close inspection of the data revealed that this result was not attributable to a number of individual cases as it was broadly represented across participants. A known MCID and future research would improve confidence in this finding. This finding led to rejection of H1(ii): *that outcomes would converge by 18 months after surgery* on the basis that a difference on the primary outcome was observed at both 12 and 18 month time points. Further exploration of the MCID of this outcome measure in future research may vary conclusions should it be shown to differ considerably from the current assertion.

7.2.4 Surgeons perceive the SVa to be more difficult

Surgeons reported that the SVa was more difficult than the MPa (mean difference 2.1/10 on the numerical assessment scale, p=0.001). In an attempt to standardise the surgical approach and familiarise surgeons not routinely performing the SVa, a senior surgeon supervised each participating surgeon performing at least five SVa approaches prior to them participating in the trial. Despite this training, it was apparent that the more experienced surgeons rated the SVa easier than did the less experienced surgeons. The literature which infers that the SVa is more difficult than the MPa argues that eversion of the patella is the main issue (Hofmann et al., 1991; Matsueda et al., 2000). The patella was not everted as part of the standardised surgical protocol in this trial and this infers that the higher difficulty ratings may relate to surgeon experience. This observation is consistent with the senior surgeon's impression on the approach who anecdotally noted that orthopaedic training registrars tend to avoid this approach when given the choice. This implies that even if the SVa did afford better outcomes, it is unclear if surgeons would be convinced to use this approach.

Implications

Every effort was made to ensure this randomised controlled trial was well designed with a rigorous methodology. Attention was given to adhering to the CONSORT statement (Moher et al., 2001) and self-calculation of the quality of methodology component score indicated this study rated 11/12 (Bourke et al., 2011). This gives every confidence that the results are trustworthy in the light of other studies with different findings. The results of the randomised controlled trial in this thesis suggest that, as well as being a more difficult surgical approach, the SVa offers no substantial benefit over the MPa, and may in fact result in inferior functional outcomes from 12 months post-operatively. In light of these findings, it would appear to be appropriate for only experienced surgeons with a particular desire to perform the SVa to attempt this procedure.

Limitations

While every effort was made to ensure the methodology of this randomised controlled trial was rigorous, there were a number of limitations which should be addressed in future clinical trials.

- A longer follow-up period beyond 18 months would have allowed it to be determined if the MPa group sustained their functional advantage on the AKSSFun over the SVa group. The intention of this randomised controlled trial, however, was to investigate the early outcomes of SVa and MPa to TKA and although follow-up was short in terms of arthroplasty follow-up, 18 months was determined sufficient for analysing the outcomes pertinent to this trial.
- No consideration was made for the effect of prosthesis type on outcome in the randomised

controlled trial. However there is no convincing evidence that the type of prostheses the surgeons used for the trial (Smith and Nephew Genesis II or LCS® Depuy Mobile-Bearing) influenced outcomes (Jacobs et al., 2001; Jacobs et al., 2005). The randomisation of participants was stratified by surgeon to mitigate any impact of prosthesis on the outcomes. Future trials may choose to utilise a single prosthesis to determine if the prosthesis has any effect on outcomes for the different approaches.

- Data on post-operative analgesia consumption was not collected in this randomised controlled trial which would have permitted more objective measurement of the variable of pain.
- No measure of intra-operative blood loss was undertaken in the randomised controlled trial. One study has found the SVa to have less intra-operative blood loss (Roysam et al., 2001), but others have not (Faure et al., 1993; Cameron, 2001; Weinhardt et al., 2004). Data on intra-operative blood loss would have enabled comparison to existing literature to help resolve this issue.
- Only participants with knee OA and those undergoing single knee procedures were included in this study. The inclusion of bilateral procedures and patients with rheumatoid arthritis would have increased participant numbers and enabled an analysis with these factors as covariates. This would have increased the generalisability of these results to these populations.
- There were a few contraventions to the surgical protocol (n=5; section 4.4) in this randomised controlled trial. A reminder to the surgeon on the trial protocol immediately prior to surgery may have eliminated avoidable breaches in protocol. A further nine participants did not progress to surgery due to medical co-morbidities. This issue may have been alleviated if randomisation occurred nearer to the time of surgery.
- Collecting data at a time frame when the patient was "ready for discharge" as determined by the physiotherapist meant that this time-point was variable (4.6±1.2 days). This was prospectively considered a strength of the design because it indicated when participants had met their discharge goals rather than the actual discharge date, which was sometimes related to organisational factors such as transport arrangements. However, for consistency within the study and for comparison with other literature (Faure et al., 1993), data at one week may be more useful in future trials.
- The results of the current trial are generalisable only to those patients eligible for a TKA on whom a SVa could be performed. The study excluded patients with co-morbidities contravening this approach, as was any patient undergoing revision TKA, or with an extension lack greater than 20 degrees or flexion of less than 70 degrees (Section 4.3.1). Thus wider extrapolation of results is not possible.

Collectively, while numerous, these limitations do not significantly impact on the quality of the current trial and are feasibly addressable in future trials.

Future directions

Evidence based practice considers the best available evidence, clinical expertise and the individual patient (Sackett et al., 1997). Future trials are required to compare the outcomes of all commonly used surgical approaches (MPa, SVa, midvastus, lateral and medial trivector). There is a growing body of evidence comparing different approaches which indicates that surgeon experience and preference, rather than clinical evidence, may ultimately determine the choice of surgical approach. It would seem that outcomes, regardless of TKA surgical approach, tend to eventually converge (Dalury et al., 1999; Keating et al., 1999; Gelfer et al., 2003; Komatsu et al., 2003; Bathis et al., 2005; Berth et al., 2007; Seyler et al., 2007; Karachalios et al., 2008; Juosponis et al., 2009; Bonutti et al., 2010; Nestor et al., 2010; Lee et al., 2011; Varnell et al., 2011). However, it would be of interest to design an innovative trial which uses the surgical approach most suited to the patient, which is performed by a surgeon with a preference for the required surgical approach.

As discussed, future trials should follow up patients in the long term, to an extent consistent with current practice in orthopaedic surgery (e.g. >10 years) and a standard time point of one week post-operatively, rather than "ready for discharge" would be better suited for early follow-up. Other functional outcomes could be of value including the Western Ontario and McMaster Universities index of osteoarthritis (WOMAC), and measures of blood loss and analgesic requirement would be of value. To ensure generalisability of results to the TKA population, future trials need to consider the impact of lateral releases, bilateral procedures, and patients with rheumatoid arthritis. Deeper investigation of why surgeons apparently perceive the SVa to be more difficult is interesting and warrants further investigation.

7.3 A comparison of patellar vascularity between the MPa and SVa in TKA

One of the proposed benefits of the SVa is that it preserves patellar vascularity (Hofmann et al., 1991). The consequences of failing to do so can be serious. Anterior knee pain and the resultant reduction in function, prosthetic loosening and the subsequent need for re-operation (Brick et al., 1989) are factors that are purported to be avoidable with the SVa (Hofmann et al., 1991).

Angiography, which is arguably the gold standard in determining blood flow in the human body, would have been best for determining patellar vascularity. This procedure, however, carries a number of unwanted risks and costs that precluded its use in this study. These risks include femoral artery cannulation, higher radiation dose, and possible reactions to the contrast medium. Considering this, two surrogate measures of vascularity were used, which carry with them inherent

limitations. Patellar vascularity was measured from three phase bone scans where Tc99m hydroxymethane diphosphonate (HDP) was administered intravenously and accumulated in bone in proportion to blood flow. The first outcome measured was the ratio of uptake of Tc99m HDP in the patella (as photon counts per pixel) to uptake in a region of interest on the distal femur (pat:fem). Referencing the patella to a region of interest on the femur minimised the effect of confounding factors such as metabolic activity of the patient (influenced by patient size, activity level), time of day, and peripheral circulation which are known to affect absolute photon counts per pixel. A new subjective clinical rating scale, termed the Bone Vascularity Scale (BVS) was also developed for this study. It is five-point scale and is used to rate patellar vascularity where: 0 = Absent, 1 = Decreased (photopenic), 2 = Normal, 3 = Mildly increased and 4 = Moderately increased. It proved to have good intra-rater (κ>0.81) and inter-rater Kappa (0.61–0.81) reliability. This quantitative method was preferred over subjective commentary which is the traditional radiological approach and can vary between radiologists. Anterior knee pain was chosen as a patient reported outcome as it is closely related to patellar avascularity (Soucacos et al., 2004).

The two methods for assessing patellar vascularity revealed concordant findings of no difference in patellar vascularity between the MPa and SVa groups at 18 months post-operatively. Furthermore, there was no difference in the experience of anterior knee pain between the MPa and SVa groups in this study. Vascularity measures on the first 10 participants in each treatment arm were used to perform an interim sample size calculation. Preliminary analysis based on pat:fem data revealed a sample size exceeding 18,000 participants would be required to adequately power a study to detect any difference.

Implications

The high number of participants required to adequately power this study was outside of the scope of the course of research in this thesis and as such the conclusions of this study should be viewed with caution, as a type two statistical error is possible. The historical notion that the SVa preserves blood supply and results in less pain was not supported by this study. Based on the results of this study, and the unlikelihood of future research being adequately powered to address this research question, it would appear that the SVa does not afford better patellar vascularity or less pain than the MPa. Therefore, the hypothesis (H2): *That the SVa would have better outcomes for vascularity and anterior knee pain than the MPa due to the extensive dissection of the patellar arterial blood supply in the latter approach* was rejected.

Knees that required lateral releases were excluded from the randomised controlled trial because it is not a procedure usually required for patients who are suitable for a SVa, due to the ability of larger quadriceps to assist patella alignment. This may have impacted on vascularity outcomes in this

study because the retention of blood supply via the supero-lateral geniculate (SLG) artery may be sufficient to retain patellar vascularity (Kayler et al., 1988). Unfortunately the exclusion of lateral releases means that the findings on vascularity of this study cannot be extrapolated to TKAs with a lateral release.

The high frequency of occasional and mild degrees of patellar avascularity observed on the outcome of pat:fem in the study sample meant that the ratios were clustered within a potentially normal range. The normal range has not as yet been established and therefore determining what is abnormal is difficult. Additionally, validation trials have not been conducted for either the pat:fem or the BVS.

The results of this research differ from claims that the SVa carries less risk of patellar avascularity (Hofmann et al., 1991). Given that the power analysis indicated that unrealistic participant numbers are required to adequately power a study to detect a difference (over 18,000 required), it is unclear whether future studies will achieve statistically significant results. Although pat:fem and BVS have face validity, and have demonstrated good intra and inter-rater reliability, future studies should establish the concurrent validity of the pat:fem and BVS against the gold standard, angiography. While content validity was established to an extent with both measures (i.e. comparing photon counts to a region of interest [ROI] on the femur rather than absolute photon counts, and using two radiologists who prospectively agreed on the meanings of each increment on the BVS), this process could be refined by comparing the photon counts of multiple technicians for the pat:fem, and undertaking "think aloud" interviews with nuclear medicine radiologists while they apply the BVS to the images. Future trials should also investigate the specificity and sensitivity of the tests, and the positive and negative predictive values of the outcomes measured and their likelihood ratio.

Once validated, pat:fem and BVS may prove to be the most feasible measures to determine the effect of surgical approach on patellar vascularity. Future studies will also require large numbers of participants and multiple surgical approaches.

7.4 Towards a model that determines when a patient with knee OA should be referred for specialist attention: a case control study

Opinions on when to refer a patient for TKA vary amongst orthopaedic surgeons, rheumatologists and primary health care providers (Dieppe et al., 1999; Cross et al., 2006). Potential indicators are numerous and include pain (Mancuso et al., 1996; Naylor et al., 1996; Hadorn et al., 1997), joint damage (Mancuso et al., 1996; Hadorn et al., 1997), functional impairment (Naylor et al., 1996; Hadorn et al., 1997), and radiographic severity of OA (Kellgren et al., 1957; Ahlback, 1968). With such a multitude of factors at play, and the inherently subjective nature of pain reporting, there is

potential for inappropriately early or delayed referral to an orthopaedic surgeon for consideration of TKA.

It was reasoned that modelling variables such as physical measures, patient-assessed scoring instruments and clinical rating systems was a plausible method to develop an indicator for when it is appropriate to refer patients to an orthopaedic surgeon. Logistic regression modelling was performed on the data from participants in the randomised controlled trial and age matched normal, pain free participants to investigate if a model could be developed which accurately predicted group association. A number of different models were trialled and a model comprising the AKSS Functional (AKSSFun) score and knee flexion range of motion out-performed the others. The AKSSFunction/Flexion model was chosen ahead of another statistical model (AKSSFunction/Extension), as the former was most sensitive to change while maintaining predictive ability and plausible odds ratios. The AKSSFunction/Flexion model accurately predicted the group allocations (TKA or control) in over 95% of participants in the sample. Therefore hypothesis H3: *That a model based on physical and functional measures can be used to quantify when it is appropriate to refer a patient to an orthopaedic surgeon* was conditionally accepted based on promising results, but with the understanding that considerable future testing is required**.**

The AKSSFunction/Flexion model synthesises common outcomes that may assist primary health care providers (e.g. general practitioners, physiotherapists) in deciding when to refer a patient to an orthopaedic surgeon for surgical management of their knee OA. It is not an attempt to simplify a referral decision to a mathematical formula. Rather the AKSSFunction/Flexion model can be used as an adjunct to aid decision-making. Whether clinicians will use the model may be dependent upon the rigour and credibility of its future development.

The construction of this initial model was limited by several important factors. First, regarding the model construct itself, the exclusion of any control participants who had knee pain but did not require a TKA as evaluated by a surgeon, meant that the predictability of the model may have been overestimated. Also, only normally distributed data of the TKA group were retained with outliers removed for the analysis. Hence the ability of the model to accommodate extreme values is unknown. Second, the sample used to test the predictive ability of the model was the same as that used to build the model and therefore the accuracy of the model may be overstated. A more rigorous testing process, conducted by blinded assessors on a new group of participants, is required. Third, the potential for selection bias in the TKA group was considered, although was partially mitigated by having six different surgeons contribute cases. Additionally, there is potential for volunteer bias since a random volunteer sample from the population for the control group was used.

The incorporation of a group of patients with knee pain but not awaiting TKA into future modelling processes is crucial to determining whether or not any modelling of referral decisions can be successful. Future studies should also strive to include patients with varying degrees of OA. Prospective studies with a larger sample with a broad spectrum of knee pathologies are required for the model to be generalisable. The accuracy of the model may be improved with these changes and the inclusion of new variables (e.g. WOMAC, 36-Item Short Form Health Survey [SF-36], European quality of life questionnaire [EuroQol]). Should a suitable model be developed, its uptake by health practitioners into clinical practice would need to be carefully evaluated.

8 Conclusion

This research compared physical and functional outcomes and patellar vascularity between the subvastus approach (SVa) and medial parapatellar approach (MPa) to TKA. The research also investigated a model to predict when a patient with knee OA should be referred for specialist care. It contributes original work that refutes current evidence suggesting that the SVa is superior to the MPa in TKA, and introduces the concept of use of physical and functional outcomes to develop a model to assist clinicians in referral decisions.

The systematic review conducted for this thesis found that there was insufficient evidence to proclaim superiority of either the MPa or SVa to TKA and recommended a methodologically rigorous trial with follow-up beyond 6 months. A randomised controlled trial of such rigour was designed, conducted and reported according to the principles of the Consolidated Standards of Reporting Trials (CONSORT) statement. This randomised controlled trial found no evidence on its primary outcome (American Knee Society Score [AKSS]) or any other outcomes in favour of the SVa except for an earlier straight leg raise (SLR; 0.9 days). It did find evidence that surgeons found the SVa more difficult and that AKSSFun component scores favoured the MPa by 12 months post-operatively. Furthermore, at 18 months, there was no difference between the approaches in anterior knee pain or vascularity of the patella. The latter was measured using the newly developed pat:fem and Bone Vascularity Scale (BVS). A preliminary model was developed which may assist primary health care providers in deciding when to refer a patient with an OA knee to an orthopaedic surgeon.

Further investigation comparing approaches other than the SVa and the standard MPa is required to establish if any affords superior outcomes. If such comparisons are to be made, consolidation of the accumulated evidence by way of a systematic review and meta-analysis should be undertaken first to guide the research. This review should examine patient and health care system impacts and present a method for comparing the approaches. Future research should investigate the physical, functional and quality of life outcomes for the individual patient, as well as outcomes that have an organisational impact, such as length of hospital stay. This should be undertaken in a trial with methodological rigour and long term follow up. Further, the approaches should be compared on the outcome of patellar vascularity, after validation trials of the pat:fem and BVS. Finally, the model to quantify when a primary health care practitioner should refer a patient with knee OA to an

orthopaedic surgeon requires further development such as the inclusion of matched participants with knee pain.

This research found no relevant evidence for supporting superiority of the SVa over the MPa. This thesis contributes original work that refutes supposition and claims in literature of this superiority. The thesis introduces novel alternate measures, without side effects, to investigate patellar vascularity and a preliminary model for use by primary health care practitioners to quantify their decision on when to refer a patient with knee OA to an orthopaedic surgeon. Directions have been provided for further research in these fields to optimise the outcomes for the growing numbers of individuals who will receive a TKA in the future.

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Appendices

Appendix 1 Quality of methodology component score

Further information is to be obtained from the primary author if the published article provides inadequate information to the review. Score I or 0

	Article identification number
Was there clear concealment of allocation?	
Were the inclusion and exclusion criteria clearly defined?	
Were the treatment and control groups adequately described at entry and if so were the groups well matched or appropriate covariance adjustment made?	
Were the surgeons experienced in the various approaches prior to the trial?	
Were the care programs other than trial options identical?	
Were the outcome measures clearly defined in the text with a definition of ambiguous terms encountered e.g. range of motion.	
Were the outcome assessors blind to assignment status?	
Was a long-term follow-up performed? Minimum of six months	
Was the timing of outcome assessment in both groups comparable and appropriate?	
Was loss to follow-up reported and if so were less than five per cent of patients lost to follow up?	
Was a sample size calculation performed?	
Did the trial include an intention-to-treat analysis?	
Level of evidence	
Total x/12	

Appendix 2 NHMRC levels of evidence used to rank articles in the review

(National Health and Medical Research Council, 2007)

Level	Intervention [§]	Diagnosis [**]	Prognosis	Aetiology [†††]	Screening
I [*]	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, [§§] among consecutive patients with a defined clinical presentation [††]	A prospective cohort study [***]	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, [§§] among non-consecutive patients with a defined clinical presentation [††]	All or none [§§§]	All or none [§§§]	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial [†] • Cohort study • Case-control study • Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study [‡] • Interrupted time series without a parallel control group	Diagnostic case-control study [††]	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard) [‡‡]	Case series, or cohort study of patients at different stages of disease	A cross-sectional study	Case series

Appendix 3 Data extraction tool

These may be split into Primary and Secondary upon reviewer advice.

	Article Identifier: A____
Number of participants	
Allocation was concealed (yes/no)	
Intervention allocation method	
Inclusion criteria were clearly defined (yes/no)	
Groups were matched at baseline or appropriate covariance adjustment was made (yes/no)	
Surgeons were experienced in both approaches (yes/no)	
Care programs other than trial options were identical (yes/no)	
Outcome measures were clearly defined (yes/no)	
Outcome assessors were blind to assignment status	
Length of follow up (months)	
Timing of outcome assessment in both groups was comparable and appropriate (yes/no)	
Timing of outcome assessment	
Percent lost to follow up	
Sample size calculation details	
Intention to treat details	
Type of approaches investigated	
Date of trial	
Location of trial	
Ethnicity of participants	
Sponsor of trial	
Publication status	
Level of evidence	
Complications (Numbers - not percent of total)	
Deep vein thrombosis	
Pulmonary embolism	
Haemarthrosis	
Haematoma	
Infection deep	
Infection superficial	
Intra-operative damage to structures	
Fractures	
Soft tissue injury	

Lateral release	
Related to the prosthesis	
Respiratory	
Mortality	
Re-operation	
Manipulation under anaesthetic	
Component loosening	
Polythene wear	
Patella mal-tracking	
Subluxation	
Other	
Post-operative outcomes	
Pain	
Knee scoring system	
American Knee Society Score	
Hospital for special surgery score	
Oxford knee score	
Other	
Health related quality of life measures	
Length of stay Days and (Cost ($))	
Days to mobilisation	
Discharge destination	
Walking aids at discharge	
Quadriceps function (ability to straight leg raise, lag on straight leg raise)	
Flexion	
Extension Lack	
Blood loss	
Patellar vascularity	
Length of surgery	
Perceived operation difficulty reported by surgeon	
Imaging results	
Other	
Other adverse outcomes	
Other economic data	
Other fields not listed above (discuss with co-reviewers and add as you go along?)	

Appendix 4 Literature review raw data sample of included articles

Study (Author, Journal year, country)	Aim	Method & length of study	Sample characteristics	Interventions & outcome measures used	Results	Comments
Cameron, Journal of Applied Research 2001 Eau Claire, Wisconsin, USA	Compare SVa and MPa on listed outcomes	Prospective analysis. Randomised by hospital registration number Bilateral had same procedure on both knees PCL sparing tricompartmental cemented replacements on all Assessed at 3/52, 3/12, 6/12, 12/12	41 TKAs (16 MPa; 25 SVa) 34 participants. 24 unilateral, 7 bilateral Age 41-88yrs. Mean SVa 66.7; MPa 69.6	Necessity for lateral release Estimated blood loss Tourniquet times Complications Pain SLR ability RoM	No LR's No diff (SVa 519, MPa 684) Tourn SVa 102, MPa91 p=0.02 Pain Day 1 SVa 2.68, MPa 4.31 p=0.0004 SLR SVa 1.12, MPa 4.31 p<0.0001 6/12 SVa 110.68, MPa 103.25 p=0.04	Not clear if only OA ???RA. Does not state how RoM collected No baseline comparison of groups.

Cila Archives of Orthopaedic Trauma Surgery 2002 Ankara, Turkey	To compare subvastus versus standard medial parapatellar approach to TKR using post-op knee scores and quadriceps strength	Prospective ?randomised study (Not controlled) 2 patient groups similar characteristics Statistically similar characteristics Freeman-Samuelson TKR System used in all patients inserted by the senior surgeon All had regional anaesthesia and inflatable tourniquet Low MW heparin. Prophylactic IV AB's for 72 hrs Preop: Alignment, Knee score & Cybex testing	Group 1: 12 knees of 9 patients MPa Group 2: 10 knees of 10 patients SubV 22 knees 19 patients. 18 female, 1 male. Primary degenerative joint disease The surgical approach was decided randomly by the surgeon All patients stood at bedside and walked Day 1 F/E exercise Day 2. No CPM or knee immobilisers were used	Knee scores and quads strength preop, post-op at week 6, 3 months, 6 months Outcome measures: Hospital for Special Surgery score Isometric & Isokinetic quads strength tests	Knee scores improved similarly but the change more pronounced in the SubV group Quads strength greater at week 6 subV. No signif diff at 3 and 6 months No DVT 1 Infection was revised	SubV offers greater quads strength in early post-operative period it has no significant advantage in this respect over the MPa Statistics very poor – no group comparisons made early. Pre/post-op change in each group Problems – poor sample size. Stats prevent re-comparison of actual muscle inhibition and knee score improvements between groups

Roysam and Oakley Journal of Arthroplasty 2001 UK	To test the hypothesis that there are no significant benefits of the subvastus approach over the standard parapatellar approach.	Prospective, randomised, patient and observer-blinded. Randomised into two groups using sealed envelopes. No significant differences between the 2 groups.	Group 1 (MPP): 43 pts (22 male, 21 female). Group 2 (SVa): 46 pts (25 male, 21 female). Mean age: MPP 69.8 yrs SVa 70.2 yrs Mean preop FFD: MPP 14.4 ° SVa 16.3 ° Mean preop flexion: MPP 71.8 ° SVa 68.6 °	All surgery performed by senior author using Insall-Burstein II prosthesis under tourniquet control, no lateral releases or patella buttons, PCA for all patients, identical skin incisions. Assessment performed by PT: first day of unassisted SLR, flexion ROM at 1wk, 4 wks and 3mths. N/staff noted: total blood loss after surgery, total consumed dose of opiates, duration of hospital stay.	Time to unassisted SLR SVa 3.2 days MPa 5.8 days (P<0.001) Total blood loss SVa 527mL MPa 748mL (P<0.001) 1st week opiate consumption SVa 78mg MPa 102mg (P<0.001) Knee flexion at 1 week SVa 78° MPa 55° (P<0.001) No significant difference in LOS, flexion at 4wks, flexion at 3mths.	No functional outcome measures. Very high LOS SVa 17.3 MPa 20.3 ?rehab intensity
Weinhardt Archives of Orthopaedic Trauma Surgery 2004	To evaluate the clinical and radiographic results immediately after TKA	Randomised prospective study 2 randomly allocated consecutive groups	52 patients 33 female 19 male 26 SVa 26 PP Diagnosis OA only Mean age	Genesis II Smith & Nephew prosthesis with patella inlay in all cases Tourniquet 400mmHg Daily gait rehab FWB	Significant difference in passive ROM. Subvastus had full knee extension and 90 flexion significantly earlier than parapatellar.	Regardless of approach, the AP tibial femoral angle improved significantly. No major

Germany	comparing the parapatellar and subvastus approach		MPa 74.4+/-7.0 yrs SVa 69.6+/-8.5 yrs Mean Operation time MPa 80+/-22mins SVa 75+/-6mins Mean blood loss MPa 264+/-120mls SVa 243+/-120mls Mean Periop blood substitution MPa 471+/-199mls SVa 312+/-215mls	Radiography – AP of complete leg to measure the leg axis correction pre & post-op. A lateral film to determine inclination of the tibial component. Xrays performed preop, immediately post-op and before discharge (mean 20.5 days) Clinical Ix included ROM, joint stability, ability of active extension from 30 flexion, ability to FWB each day, pain documented by VAS	SVa 90°F D7+/-2.4 0°Ext D2.2+/-2.6 SLR D8.3+/-2.8 PP 90°F D11+/-4.2 Poorer Ext results SLR D12+/-3.1 On discharge both groups were comparable Analogous results in both groups on radiological assessment 48 required valgus/varus correction No complications No significant difference in patient overall satisfaction	differences could be seen concerning pain, operation time, blood loss, blood substitution and complications Advise wider use in primary TKR

					Significant improvement in pain since preop both groups – SVa slightly lower	
Faure et al Journal of Arthroplasty 1993 USA	Assess the relative benefits of the SVa and MPa surgical exposures on the patient's post-op recovery.	Prospective, randomised clinical trial. Follow-up to 3 months post-op. Performed on 20 patients undergoing one stage bilateral TKA. Random selection decided by the senior surgeon at the time of surgery.	20 patients: 11 men, 9 women. Mean age: 70 yrs 14 bilateral TKA, 6 bilateral UKA Mean Preop ROM 6 – 112 °.	Strength testing and ROM at Preop, 1 week, 1 month, 3 months using LIDO device. Performed by a single blinded assessor. Identical surgical procedure (excluding approach). Bedside PT on 1st postop day, with knee ROM and ambulation commencing Day 2. CPM if flexion <60° or lag >20°.	Strength: At 1 week – SVa 35% greater strength on 60°/sec testing, 38% greater on 120°/sec test. At 1 month – SVa 16% and 12% greater respectively. No significant difference at 3 months. Tourniquet time: PP 71 mins SVa 74 mins (not significant) Drainage: PP 411mL SVa 375mL No significant difference between surgical approaches. No difference in post-op ROM between PP and SVa. 5 lateral releases in PP, 2 in SVa	No functional outcome measures. Allocation decided by surgeon.

Appendix 5 Ethics approval correspondence - randomised controlled trial

Princess Alexandra Hospital
Health Service District

Queensland Government

Queensland **Health**

Mr Michael Bourke
Senior Physiotherapist – Orthopaedics
QEII Jubilee Hospital
PMB 2 Acacia Ridge
BRISBANE QLD 4110

Enquiries to:	PAH Human Research Ethics Committee
Telephone:	3240 7672
TTY:	07 3240 7737
Facsimile:	3240 7667
Email:	Anne_Walsh@health.qld.gov.au
Our Ref:	2005/191
Date:	31 January 2006

Dear Mr Bourke

Re: 2005/191
"An Evaluation of the Clinical Outcomes of the Aubvastus Verses the Medial Parapatella Approach to Total Knee Replacement."

At the 2 November 2005 Human Research Ethics Committee meeting the above study was reviewed. The Committee has received satisfactory responses to the issues raised and full approval is recommended.

The following documents where reviewed:

- Research Proposal, including appendices;
- Participant Information Sheet and Consent Form;
- Queensland X-Ray Patient Information Sheet;
- Consent form for release for use of images or recordings

This Committee is constituted and operates in accordance with current NHMRC Guidelines.

If any substantial change is made to the protocol, this will need to be approved by the Committee. Submission of an amendment or extension to the protocol must give sufficient time and detail for formal consideration. The Committee must also be informed of any problems that arise during the course of the project which may have ethical implications. Serious adverse events must be notified to the Committee as soon as possible. If the study has not commenced within two years approval will lapse.

A NHMRC requirement is that all projects be reviewed annually. Accordingly, a short questionnaire will be sent to you every 12 months after initial approval and your assistance in completing and returning this promptly would be appreciated.

When the study involves patient contact, it is your responsibility as the principal investigator to notify the relevant consultant and request their approval.

A copy of this letter should be presented when required as official confirmation of the approval of the PAH Human Research Ethics Committee.

Office	Postal	Phone	Fax
Princess Alexandra Hospital Health Service District	Ipswich Road Woolloongabba Q 4102	61 7 3240 2111	61 7 3240 5677

The letter with a copy of the protocol (if not already submitted) must be given to the District Manager of the Queen Elizabeth II Hospital Health Service District for approval before the study can be conducted there.

Best wishes for the progress of the study.

Yours sincerely

Gwynneth Petrie

Ms Gwynneth Petrie
Acting Chair
Human Research Ethics Committee
PRINCESS ALEXANDRA HOSPITAL HEALTH SERVICE DISTRICT

13/2/06

Princess Alexandra Hospital
Health Service District

Queensland Government

Queensland **Health**

Enquiries to:	PAH Human Research Ethics Committee
Telephone:	3240 7672
TTY:	07 3240 7737
Facsimile:	3240 7667
Email:	PAH_Ethics_Researc h@health.qld.gov.au
Our Ref:	2005/191
Date:	7 November 2007

Mr Michael Bourke
Physiotherapy Department
QEII Jubilee Hospita
PMB2
Acacia Ridge 4110

Dear Mr Bourke

Re: 2005/191
An Evaluation of the Clinical Outcomes of the Subvastus Versus the Medial Parapatella Approach to Total Knee Replacement.

On the 5 November 2007 the Princess Alexandra Hospital Human Research Ethics Committee Chair executively reviewed the following amendment(s) for the above study and approval was granted:

- Letter dated 19 October 2007, outlining an amendment to the method of bone scanning to allow better assessment of patella vascularity.

It should be noted that all requirements of the original approval still apply.

If you have any queries, please do not hesitate to contact the Princess Alexandra Hospital Human Research Ethics Committee Executive Support Officer on (07) 3240 7672.

Best wishes for the progress of the study.

Yours sincerely

Ms Gwynneth Petrie
Chair
Human Research Ethics Committee
Princess Alexandra Hospital Health Service District

THE UNIVERSITY OF QUEENSLAND

Institutional Approval Form For Experiments On Humans Including Behavioural Research

Chief Investigator:	Mr Michael Bourke
Project Title:	Evaluation Of The Clinical Outcomes Of The Subvastus Versus The Medial Parapatella Approach To Total Knee Replacement
Supervisor:	Dr Trevor Russell
Co-Investigator(s)	Dr Trevor Russell, Mr Peter Buttrum, Dr Philip Dalton, Dr Mark Dekkers, Dr Cameron Cooke, Dr Prue Fitzpatrick, Dr Jim Curtis, Dr John Dodsworth, Dr Gary Nielsen, Dr Ross Kennedy
Department(s):	School of Health and Rehabilitation Sciences, Division of Physiotherapy
Project Number:	2006000154
Granting Agency/Degree:	Queensland Health Innovation Board
Duration:	30th September 2009

Comments:

Expedited review on the basis of approval from the Princess Alexandra Hospital HREC dated 31/01/2006.

Name of responsible Committee:-
Medical Research Ethics Committee
This project complies with the provisions contained in the *National Statement on Ethical Conduct in Research Involving Humans* and complies with the regulations governing experimentation on humans.

Name of Ethics Committee representative:-
Dr Bill Vicenzino
Chairperson
Medical Research Ethics Committee

Date: 08.03.2006 Signature:

Appendix 6 Participant information and consent forms - randomised controlled trial

PARTICIPANT INFORMATION SHEET – QEII JUBILEE HOSPITAL

PROJECT TITLE	***An evaluation of the clinical outcomes of the subvastus versus the medial parapatellar approach to total knee replacement.***
LAY TITLE	***The effectiveness of a medial approach to knee replacement compared to a subvastus approach.***
INVESTIGATORS	***All members of the research team are contactable on 07 3275 6331 where they may be paged by reception staff. The after hours contact is 3275 6111. Michael Bourke's direct contact number is 3275 6173.***

Michael Bourke Senior Physiotherapist – Orthopaedics, QEII Jubilee Hospital
Peter Buttrum Director of Physiotherapy, QEII Jubilee Hospital
Dr Philip Dalton Director of Orthopaedic Surgery, QEII Jubilee Hospital
Dr Mark Dekkers Asst. Director of Orthopaedics, Princess Alexandra Hospital
Dr John Dodsworth Orthopaedic Surgeon, QEII Jubilee Hospital
Dr Peter Johnstone Orthopaedic Surgeon, QEII Jubilee Hospital
Dr Prue Fitzpatrick Orthopaedic Surgeon, QEII Jubilee Hospital
Dr Ross Kennedy Orthopaedic Surgeon, QEII Jubilee Hospital
Dr Gary Nielsen Orthopaedic Surgeon, QEII Jubilee Hospital
Dr Trevor Russell , Department of Physiotherapy, University of Queensland.

You have elected to have a Total Knee Replacement. This process involves preparation for surgery and rehabilitation after surgery. The rehabilitation phase of your recovery is split into two parts, inpatient rehabilitation, while you are still on the ward, and outpatient rehabilitation. We would like your help in investigating the difference between two types of surgical approach to knee replacement surgery which are both commonly used at QEII Jubilee Hospital. There are no risks involved in this study outside of the risks associated with routine knee replacement surgery

If you agree to participate in the study, you will be randomly assigned to one of two groups; like the toss of a coin. Group one will consist of participants having a medial parapatellar approach to knee replacement. Group two will have a subvastus approach. The medial parapatellar approach is the more common of these routine procedures. During this approach the quadriceps (thigh) muscle is cut so the surgeon has enough room to replace your knee. In the subvastus approach the surgeon

goes under the quadriceps to replace your knee. You will not be told which approach you are having. This is important to ensure the study is impartial. Regardless of which group you are assigned to, you will undergo standard preparation and rehabilitation for your operation. You will be required to attend follow-up Doctor and Physiotherapy appointments at two weeks, six weeks, six months and 12 months after your operation. At these follow-up appointments the Doctors and Physiotherapists will measure your knee motion, girth, strength and function. As part of this study, at 18 months you will be required to have a bone scan of your knee to check its blood supply. All protocols and rehabilitation for your operation will be identical across both groups. For this study you will need to consent for photography of your knee.

You will be required to undergo a number of assessments at six weeks, six months and 12 months. At these assessments, the following will occur:

1. Questions about your ability to function will be asked
2. You will be required to undergo physical assessments of your knee similar to those normally expected in a knee examination. Such things as knee range of motion, muscle strength and swelling.
3. A Bone Scan of your knee will be requested 18 months after you have been discharged from hospital to assess the blood supply to your knee cap. This is not a routine procedure after knee replacement surgery. It is only being done for the purpose of this study. Please review the attached information sheet from Queensland X-Ray which explains in detail the risks of a bone scan.

You can elect to participate in the study but not have a bone scan. Simply tick the box indicating your preference on the Participant Consent Form

None of the assessments performed during the study will cause any pain beyond that normally encountered with physical knee assessment and rehabilitation after knee replacement.

Participation in this study is on a voluntary basis and you reserve the right to withdraw at any time from the study for any reason, without any penalty and without affecting any further treatment or relations with the QEII Jubilee Hospital. Should you elect not to participate in the study you will continue to follow the standard process for knee replacement surgery. In discussion with your surgeon you can decide which type of surgery will be performed rather than being randomly allocated a type of surgery. In order for the researchers to accurately assess the effectiveness of

your knee replacement, we request that you continue with the prescribed exercises and physiotherapy treatment as instructed by your physiotherapist.

Your confidentiality will be maintained at all times throughout the study and you will in no way be identified in any publication or report. Furthermore, you will be assigned a number that will be used, rather than your name, on all stored information. All assessment measures will be stored in a lockable cabinet in the Physiotherapy Department at the QEII Jubilee Hospital. Data collected with computer technology will be stored in a password protected secure database in coded format and will be available only to those researchers directly involved in this research. De-identified data will be stored for a maximum of fifteen years upon completion of the study.

A copy of the outcomes of this study will be available from the Physiotherapy Department at the QEII Jubilee Hospital for your interest at the completion of the study in January 2010. Additionally, you are invited to attend QEII Physiotherapy Department on completion of the study where the results of the study will be available. The information gathered from this study will assist Orthopaedic Surgeons determine the most appropriate surgical approach to knee replacement.

Both the QEII Jubilee Hospital and the University of Queensland ethics committees have given ethical clearance for this study. You are free to discuss your participation in this study with the project staff on 3275 6173, however, if you would like to speak to an officer not involved in the study, you may contact the Ethics Officer at the University of Queensland on 3365 3924. The Princess Alexandra Hospital Research Ethics Committee (acting for the QEII Jubilee Hospital) may be contacted on 3240 5856.

By consenting to participate in this study you give members of the research team permission to access your medical record for the purpose of the study. This study is being conducted as part of a requirement for a Physiotherapy higher research degree at the University of Queensland, Brisbane, Australia.

Photographic Consent Form Information

Important note:

Important information explaining this consent is located on the next page of this consent form. You may request a copy of this information at any time.

IMPORTANT PRIVACY INFORMATION:

The Department is collecting the information contained in this form to verify your consent for use of your image or recording for the purposes contained in the consent form. Your consent to the use of your personal information is required in accordance with the Queensland Government's Information Privacy Standard 42. The information privacy principles contained within this Standard govern the collection, use, storage, security, and disclosure of personal information. Only authorised Departmental officers have access to this information. From time to time the Department may provide some or all of this material to other government departments and agencies, or to recognised media outlets for their use to promote Departmental programs, services and initiatives as outlined above. Your personal information contained in this form will not be disclosed to any other third party without your consent, unless authorised or required by law. If you have any queries about any privacy issues that relate to this consent form then please contact the Department's privacy contact officer.

EXPLANATORY NOTES FOR THE PARTICIPANT

What is this consent for?

This consent form authorises the Department to use the specified image or recording of the participant, together with information about their participation in Departmental initiatives, in publications, productions and presentations in connection with the Department's work. The consent extends to use of the image or recording in whole or part and digital adaptations used alone or in conjunction with words, drawings and other images.

What sort of publications could this material appear in?

This material can appear in television advertising, videos, brochures, forms, public relations displays, annual reports, press advertising, internal documents such as manuals, web sites, certificates, strategic plan, posters and promotional material and other materials produced by the Department. The images and recordings may also be used by other government departments and agencies for similar purposes (if authorised).

What is an image or recording?

An image or recording referred to in this consent form includes photographs, videos, films, or sound recordings of the Participant.

Who is a child?

A child is defined as any person who has not yet turned 18 years of age.

Who is a person with a decision-making disability?

For the purposes of this consent form, a person with a decision making disability is a person who cannot give consent because they lack capacity or have an intellectual or other impairment that affects their capacity to consent. If a person is an adult and unable to give consent, an authorised decision-maker must give consent on the person's behalf (see for example *Powers of Attorney Act 1998* and/or the *Guardianship and Administration Act 2000*).

What happens to the consent form once it is filled out?

The consent form is retained by the Department and will be placed on file. A copy will be provided to the Participant.

Modification or Withdrawal of consent

Consent can be modified or withdrawn in writing at any time however, any changes will only apply from the date of receipt by the Department. Any existing material in which the image or recording is used will not be withdrawn from use.

Produced by Media and Communication Unit, Queensland Health

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CONSENT FORM FOR PARTICIPATION IN STUDY
QEII JUBILEE HOSPITAL

PROJECT TITLE	An evaluation of the clinical outcomes of the subvastus versus the medial parapatellar approach to total knee replacement	
LAY TITLE	The effectiveness of a medial approach to knee replacement compared to a subvastus approach	
INVESTIGATORS	Michael Bourke	Senior Physiotherapist – Orthopaedics, QEII Jubilee Hospital
	Peter Buttrum	Director of Physiotherapy, QEII Jubilee Hospital
	Dr James Curtis	Orthopaedic Surgeon, QEII Jubilee Hospital
	Dr Philip Dalton	Director of Orthopaedic Surgery, QEII Jubilee Hospital
	Dr Mark Dekkers	Asst. Director of Orthopaedics, Princess Alexandra Hospital
	Dr John Dodsworth	Orthopaedic Surgeon, QEII Jubilee Hospital
	Dr Peter Johnstone	Orthopaedic Surgeon, QEII Jubilee Hospital
	Dr Prue Fitzpatrick	Orthopaedic Surgeon, QEII Jubilee Hospital
	Dr Ross Kennedy	Orthopaedic Surgeon, QEII Jubilee Hospital
	Dr Trevor Russell	Lecturer, Department of Physiotherapy,

I _____*(print participant's name)* consent to take part in the above study.
I have read the attached Participant Information Sheet. I understand the nature and purpose of this randomised study and any side-effects or risks involved.

All my questions have been answered to my satisfaction. I acknowledge that my involvement in the study may not be of benefit to me. The opportunity has been given to me to have a friend or relative present when the study was explained. I understand that taking part in the study is voluntary and I am free to withdraw at any time I wish and this will not affect my clinical management.

I understand that all the information gained in the study will be treated confidentially.

I give permission for the research team to access my medical record.

Please tick ***one*** of the following options:

- ☐ I elect to have a bone scan as part of this study
- ☐ I do not wish to have a bone scan as part this study

Participant: _____ Print name:_____ Date:___/___/___

Witness:_____ Print name:_____ Date:___/___/___

I have explained the nature and purpose of this study to the above participant and have answered their questions.

Investigating ***Consultant*** Surgeon:_____ Date:_____

Appendix 7 Excerpt from the Queensland Health total knee replacement clinical pathway

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

Clinical Pathway — Knee Arthroplasty

EXPECTED OUTCOMES –

Phase: 1 **Assessment at Pre-Admission**
- You can state the reason for admission, surgery and how long you will be in hospital.
- That all relevant investigations have been completed and the results reviewed.

Phase: 2 **Pre- and Post-Operation**
- After the results have been explained, you can state an understanding of the usual pre- and post-operative care routines, the surgery and its effects.
- Your pain will be in a range that is OK with you, both before and after your operation.
- As soon as you are alert and orientated, you will not feel sick and can drink again. As soon as you are assessed as ready, you will also be able to eat.

Phase: 3 **Day 1 Post-Operative**
- The Orthopaedic Surgical Team will have reviewed your progress.
- You will be drinking and eating normally now.

Phase: 4 **Day 2 – 7 Post-Operative until ready for discharge**
- The Orthopaedic Surgical Team will continue to review you daily and once you are ready, will suggest follow-up.
- The physiotherapist will help you to walk until you can do it by yourself.

Phase: 5 **Discharge**
- When the Doctor says you are ready to go home, whether on day five or later, your care providers will follow the Discharge Planning Checklist and you will be able to go home.

	Key Milestone (steps)	Pre-adm Clin.	Admit	Pre-Op	Post-Op	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
	Date											
1.	Placed on pathway											
2.	Assessed by Ortho Team											
3.	Blood tests, X-rays etc will be taken											
4.	IV fluids commenced											
5.	Prepared for surgery											
6.	Transferred to surgery											
7.	Post-operation vital signs											
8.	Not feeling sick and pain level ok											
9.	Awake and know where you are											
10.	Wound ooze minimal											
11.	Can pass urine after operation											
12.	Drains removed											
13.	Compression device removed											
14.	IV Cannula removed											
15.	Drinking / eating normally											
16.	Reviewed by Orthopaedic team											
17.	Can walk with 2 sticks safely											
18.	Ready to go home											
19.	Carer available on going home.											
20.	Discharge check list completed											

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ♣ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category		Date ___/___/___ **POST-OP DAY OF SURGERY**	Time	Sign	Variance
Reviews	▲	Time returned to ward:			
	■	Consultant / Registrar / RMO (Circle)			
		Antibiotic cover ordered for IDC insertion			
		Post-operative instructions (IF NOT ON ORMIS):			

			AM	PM	ND	V
Investigation		Post-operative knee x-ray performed				
Medications Pain Management	▲	Medications / Pain relief / Antibiotics given as ordered				
	■	**Pain Management**: ☐ PCA ☐ Infusion ☐ Epidural ☐ IMI ☐ Oral				
	▲	Analgesia adequate / effective and without ill effects				
Observations Treatments	▲	Post op Observations and wound checks attended				
		Acute Pain Management form and protocols completed				
		Neuro vascular obs performed				
		IV cannula – patent, no signs of inflammation				
		Anti-embolic therapies continues				
		Fluid balance chart maintained				
		Deep breathing and leg exercises performed				
		Waterlow Pressure Ulcer assessment reviewed SCORE:_____				
		Fall risk assessment tool reviewed SCORE_____				
Nutrition	▲	Once alert, sips of water increasing to diet and fluids				
Hygiene Elimination	▲	Hygiene needs attended – post-op sponge / pressure area care				
		No sign of urinary retention If IDC insitu - output > 50mls hour				
Wound and Dressings	▲	Dressing intact, wound ooze minimal				
		Drain insitu Yes / No				
		Reinfusion drains reinfused within 6 hours				
Activity Mobility	▲	Resting in bed				
		Breathing and circulation exercises encouraged				
Patient Education & Discharge Planning	▲	Patient given explanation / understands treatment course				
		Patient given support and reassurance				

Expected Outcomes		**Nurse to assess: A – Achieved V - Variance**	A	V
	▲			
	3.1	Patient understands usual pre- and post-operative care routines, the surgery and its effects.		
	3.2	Management of patient pain ensures a level of discomfort that is acceptable for the patient.		
	3.3	Post-operatively – once alert and orientated may resume an oral fluid intake and diet		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
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Given Names _____
Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ♣ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category	Key	POST-OP DAY 1 Date ___/___/___	Time	Sign	Variance
Reviews	■	Consultant / Registrar / RMO (Circle) ☐ Afebrile ☐ Wound satisfactory Post-op knee X-rayed Drain removal ordered			
		Plan			

Category	Key		AM	PM	ND	V
Investigations	■	Pathology within expected range HB checked Hb_____				
Medications Pain Management	▲	Given as ordered on medication chart				
	■	Pain management reviewed first by Acute Pain Service				
	Ⓟ	Medications reviewed and plan confirmed				
Epidural / PCA	▲	PCA/ Epidural: Femoral / Lumbar block obs performed				
		PCA / Epidural: Femoral / Lumbar block site satisfactory				
Observations Treatments	■▲	Compete Acute Pain Management Document as per protocol				
		IV cannula site – patent, no signs of inflammation				
		Observations within patient's normal limits				
		Anti-embolic therapies continues				
		Fluid balance form completed				
		Waterlow Pressure Ulcer assessment reviewed SCORE: _____				
		Fall risk assessment tool reviewed SCORE_____				
Nutrition	▲	IV Therapy Continued				
		No nausea or vomiting				
Hygiene Elimination	▲	Sponge in bed / Pressure area care attended				
		No sign of urinary retention (If IDC insitu - output > 50mls hour)				
Wound and Dressings	▲	Dressing Reviewed: Intact (reinforced if wet.)				
		Drains removed as ordered & checked by two RN's 1) _____ 2) _____				
Activity / Mobility	◆	Chest and calves check NAD				
		Breathing & circulation exercises – foot/ankle/static quads & gluts				
		Active knee flex to___°, Ext lack____°, SLR Y☐ N☐ with____°lag				
		Stand / Walk in rollator, Y☐ N ☐, assist x 1 ☐ or 2 ☐				
		Weight Bearing Status - FWB, PWB, TWB, NWB (circle)				
		Cold therapy applied and skin test / warning given				
		Comments:				
Patient Education	■ ▲	Level of activity, wound care, diet and pain management explained & discussed				

Expected Outcomes	Key	Patient demonstrates: A – Achieved V - Variance	A	V
	▲			
	3.1	Orthopaedic team has reviewed patient's progress and explained their plan		
	3.2	Patient will be eating and drinking normally now		
	3.3	Pain controlled at rest		
	3.4	Observations within normal limits		
	3.5	Patient can transfer to stand with assistance		
	3.6	Haemodynamically stable		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F
Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ♣ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category		POST-OP DAY 2 Date ___/___/___	Time	Sign	Variance
Reviews	■	Consultant / Registrar / RMO (Circle) ☐Afebrile ☐ Wound satisfactory Review IV Access / Fluids			
		Plan:			

			AM	PM	ND	V
Investigations	■					
Medications Pain Management	■ ▲	Given as ordered on medication chart				
		Pain management reviewed by Acute Pain Service				
	Ⓟ	Medications reviewed and plan confirmed				
Epidural / PCA	▲	PCA/Epidural: Femoral /Lumbar observations performed & removed				
Observations Treatments	▲	Observations within patient's normal limits				
		Anti-embolic therapies continues				
		Waterlow Pressure Ulcer assessment reviewed SCORE: _____				
		Fall risk assessment tool reviewed SCORE_____				
Nutrition	▲	IV Therapy discontinued				
		Tolerating full diet and free fluids				
		No nausea or vomiting				
Hygiene Elimination	▲	Showered with assistance				
		Elimination recorded				
		Fluid Balance Chart ceased				
Wound and Dressings	▲	Dressing Reviewed: Changed / Reinforced				
Activity /Mobility	◆	Calf and chest check & NAD, breathing & circulation exercises				
		Active knee flex to___°, Ext lack____°, SLR Y☐ N☐ with____° lag				
		Mobility aid_____, assist _____distance _____ m.				
		Sit out of bed Y☐ N☐ Cold therapy applied				
		Comments:				
Patient Education & Discharge Planning	♣	Recommendations / plan made at pre admission clinic reviewed				
		Reinforced implications of surgery for ADL's				
		Encouraged independence in ADL's and strategies developed				
		Day 2 OT interventions completed on Day __/__/__				
		Comments:				

Expected Outcomes		Patient demonstrates: A – Achieved V - Variance	A	V
	▲ 4.1	Orthopaedic Team has review patient's progress and follow up care planned		
	4.2	Patient drinking and eating normally		
	4.3	Patient's pain is controlled		
	4.4	Patient mobilising with rollator and assistance		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ♣ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category	Key	POST-OP DAY 3 Date ___/___/___	Time	Sign	Variance
Medical	■	Consultant / Registrar / RMO (Circle) ☐ Afebrile ☐ Wound satisfactory Anticoagulant Therapy ☐ Yes ☐ No			
		Plan:			

			AM	PM	ND	V
Investigations	▲	INR checked (if on warfarin)				
Medications Pain Management	■▲	Given as ordered on medication chart				
		Pain management reviewed by Acute Pain Serviced				
	Ⓟ	Medications reviewed and plan confirmed				
Observations Treatments	▲	Observations within patient's normal limits				
		Anti-embolic therapies continues				
		Waterlow Pressure Ulcer assessment reviewed SCORE:_____				
		Fall risk assessment tool reviewed SCORE_____				
Nutrition	▲	IV Therapy discontinued				
		Tolerating full diet and free fluids				
Hygiene Elimination	▲	Toileted / showered in high perched chair assist x1				
		IDC removed				
		Bowels opened				
Wound and Dressings	▲	Wound assessed – no excess redness or swelling / incision apposed, dressed with _____				
Activity / Mobility	◆	Chest & calf check NAD, breathing & circulation exercises				
		Active knee flex to___°, Ext lack____°, SLR Y☐ N☐ with____° lag				
		Mobility: aid _____assist_____ distance ____m.				
		Cold therapy applied				
		Comments:				
Patient Education & Discharge Planning	■▲	Levels of activity, wound care, diet and pain management explained and discussed				
		Signs and symptoms requiring medical advice after discharge explained and discussed				

Expected Outcomes	▲	Patient demonstrates: A – Achieved V - Variance	A	V
	4.1	Orthopaedic team has reviewed patient's progress and follow up care planned		
	4.2	Patient tolerating diet and fluids		
	4.3	Able to shower with assistance and minimal discomfort		
	4.4	Incision free from signs of infection		
	4.5	Patient remains afebrile		
	4.6	Pain is controlled		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ♣ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category	Key	POST-OP DAY 4 Date ___/___/___	Time	Sign	Variance
Medical	■	Consultant / Registrar / RMO (Circle)			
		Afebrile ☐ Wound intact			
		Anticoagulation therapy within normal limits			
		Proceeding according to Clinical Pathway			
		Plan			

Category	Key		AM	PM	ND	V
Investigations		FBC and Hb within normal range				
Medications Pain Management	■	Given as ordered on medication chart				
	▲	Medications reviewed and plan confirmed				
Observations Treatments	▲	Observations within patient's normal limits				
		Anti-embolic therapies continues				
		Waterlow Pressure Ulcer assessment reviewed SCORE:_____				
		Fall risk assessment tool reviewed SCORE_____				
Nutrition	▲	Tolerating full diet and free fluids				
		No nausea or vomiting				
Hygiene Elimination	▲	Toileted / showered assist x 1				
		Bowels opened				
Wound and Dressings	▲	Wound redressed with:				
Activity / Mobility	◆	Chest & calf checked & NAD, breathing / circulation exercises				
		Active knee flex to___°, Ext lack____°, SLR Y☐ N☐ with____° lag				
		Mobility: aid _____ assist_____ distance _____m stairs____				
		Comments:				
Patient Education & Discharge Planning	▲	Pain management explained and discussed				
		Mobility aids organised				
	◆	Post D/C physiotherapy required				

Expected Outcomes	Key	Patient demonstrates: A – Achieved V - Variance	A	V
	▲			
	4.1	Orthopaedic team has reviewed patient's progress		
	4.2	All follow-up arrangements made		
	4.3	Patient transferring independently		
	4.4	Patient performing exercise program independently		
	4.5	Educate re: wound care		
	4.6	Pain controlled		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ♣ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category		POST-OP DAY 5 Date ___/___/___	Time	Sign	Variance
Medical	■	Consultant / Registrar / RMO (Circle)			
		☐ Afebrile ☐ Wound intact			
		Anticoagulant Therapy within normal limits			
		Plan:			

			AM	PM	ND	V
Medications Pain Management Observations Treatments	■▲	Given as ordered on medication chart				
	Ⓟ	Medications reviewed and plan confirmed				
	▲	Observations within patient's normal limits				
		Anti-embolic therapies continues				
		Waterlow Pressure Ulcer assessment reviewed SCORE:_____				
		Fall risk assessment tool reviewed SCORE_____				
Nutrition	▲	Tolerating full diet and free fluids				
		No nausea or vomiting				
Hygiene Elimination	▲	Toileted / showered assist x 1				
		Bowels opened				
Wound and Dressings	▲	Wound dry & dressing applied Type:_____				
Activity / Mobility	◆	Chest & calf check, breathing / circulation exercises				
		Review independent exercise program, practise transfers & gait				
		Active knee flex to___°, Ext lack____°, SLR Y☐ N☐ with____°lag				
		Mobility: aid_____ assist_____ distance _____m stairs_____				
		Comments:				
Occupational Therapy	♣	Independence with ADL's reviewed ☐ Indep ☐Assist _____				
		Shower / bath transfers reviewed ☐ Indep ☐Assist_____				
		Toilet transfers reviewed ☐ Indep ☐ Assist_____				
		Reinforced precautions & finalise equipment needs				
		Day 5 OT interventions completed on __/__/__				
		Comments:				
Patient Education & Discharge Planning	▲	Levels of activity, wound care, diet and pain management explained and discussed				
		Community services contacted				
		QAS booked if applicable				
	◆	Reinforce Home Exercise Program in home environment				
		Discharge plan commenced				

Expected Outcomes	▲	Patient demonstrates: A – Achieved V - Variance	A	V
	4.1	Orthopaedic team has reviewed patient's progress		
	4.2	Discharge arrangements completed		
	4.3	Pre-op bowel & bladder habits back to normal		
	4.4	Pain controlled		
	4.5	Patient mobilising with supervision		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F
Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ♣ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category	Key	POST-OP DAY 6 Date ___/___/___	Time	Sign	Variance
Medical	■	Consultant / Registrar / RMO (Circle)			
		☐ Afebrile ☐ Wound intact			
		Discharge medication ordered			
		Follow Up appointment confirmed			
		Plan:			

			AM	PM	ND	V
Investigations						
Medications Pain Management	■ ▲ Ⓟ	Given as ordered on medication chart				
		Medications reviewed and plan confirmed				
Observations Treatments	▲	Observations within patient's normal limits				
		Anti-embolic therapies continues				
		Waterlow Pressure Ulcer assessment reviewed SCORE:_____				
		Fall risk assessment tool reviewed SCORE_____				
Nutrition	▲	Tolerating usual diet and free fluids				
Hygiene Elimination	▲	Maintaining hygiene independently				
		Bowels opened				
Wound and Dressings	▲	Wound dry, dressing applied, Type:_____				
Activity / Mobility	◆	Chest & calf checked & NAD, breathing & circulation exercises				
		Review independent exercise program practice transfer and gait				
		Active knee flex to___°, Ext lack___°, SLR Y☐ N☐ with___° lag				
		Mobility: aid_____ assist_____ distance _____m stairs_____				
		Comments:				
Patient Education & Discharge Planning	▲	Levels of activity, it's benefits, wound care, diet and pain management explained and discussed				
		Discharge plan commenced				

			A	V
Expected Outcomes	▲	**Patient demonstrates: A – Achieved V - Variance**		
	4.1	Orthopaedic team has reviewed patient's progress		
	4.2	All follow-up arrangements made		
	4.3	Patient and family understand discharge plan		
	4.4	Patient mobilising independently		
	4.5	Patient understands home exercise program		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____
Family Name _____
Given Names _____
Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

All care givers who initial are to sign signature log

Key ■ Medical ▲ Nursing ✚ Occupational Therapy Ⓟ Pharmacy ◆ Physiotherapy

Category		Date ___/___/___ **POST-OP – Day 7 DAY OF DISCHARGE**	Time	Sign	Variance
Medical	■	Consultant / Registrar / RMO (Circle)			
		☐ Afebrile ☐ Wound free of infection			
		Anticoagulant Therapy within normal limits			
		Follow-up appointment made			
		Plan:			

			AM	PM	ND	V
Medications Pain Management	■ ▲ Ⓟ	Given as ordered on medication chart				
		Discharge medications given to patient & education				
Nutrition	▲	Tolerating usual diet and fluids Patient experiencing no nausea or vomiting				
Hygiene Elimination	▲	Tolerating usual diet and free fluids				
		Bowels opened				
Wound and Dressings	▲	Wound dry, water proof dressing applied				
Observations	▲	Observations within patient's normal limits				
		Waterlow Pressure Ulcer assessment reviewed SCORE:_____				
		Fall risk assessment tool reviewed SCORE_____				
Activity / Mobility	◆	Chest & calf checked & NAD, breathing & circulation exercises				
		Review independent exercise program practice transfer and gait				
		Active knee flex to___°, Ext lack____°, SLR Y☐ N☐ with____° lag				
		Mobility: aid_____ assist_____ distance _____m stairs_____				
		Comments:				
Patient Education & Discharge Planning	▲	Levels of activity, wound care, diet and pain management explained and discussed				
		Clip remover provided				
		Courtesy call to relatives / nursing home / hostel re d/c				
		Discharge plan provided and instructions given				
		Discharge plan completed				

			A	V
Expected Outcomes	▲	**Patient demonstrates: A – Achieved V - Variance**		
	4.1	Orthopaedic team has reviewed patient's progress		
	4.2	All follow-up arrangements made and patient ready for discharge		
	4.3	Discharge letter given to patient on discharge		
	4.4	Patient and family understand after care responsibilities		
	4.5	Patient understands dispensing of medications		
	4.6	Patient mobilising independently & independent with home exercise program		

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Total Knee Arthroplasty Clinical Pathway

Facility:

UR Number _____

Family Name _____

Given Names _____

Date of Birth _____ Sex ☐ M ☐ F

Affix patient label here

Discharge Plan / Summary

MEDICAL	Sign	Date
Referral Source notified of discharge		
GP/Practice		
Referral Dr		
Referral Hospital		
Discharge Letter		
Copy given to patient		
Sent to GP ☐ Faxed ☐ Mailed		
Advice provided regarding		
Return to normal activities		
Follow-up plan confirmed		
When to seek medical assistance		
Emergency number _____ given		
Medical certificate / Travel documents		
Completed		
Issued		
Follow-up		
In _____ weeks		
On ____ / ____ / _____		
GP time:_____		
OPD time:_____		
Other:_____		
Discharge Medication Ordered		
MEDICATIONS		
Drug Profile print out provided for at risk patients		
Discharge medications given to patient and educated re: regime		
Medication Discharge Summary provided to patient		
Discharge Summary / Referral Form faxed to GP		
Time faxed _____		
OCCUPATIONAL THERAPY		
♣ Appropriate ADL function for discharge or strategies in place		
♣ Understands impact of surgery on ADL's and home environment		
♣ Discharge equipment / home mods in place & patient demonstrate appropriate use.		
Occupational Therapy referral to:-		
Comments		

NURSING	Sign	Date
Support Person		
Support Person notified of discharge @_____hrs		
QAS booked 24hrs prior to discharge		
Patient transported home by_____		
Belongings and Valuables Returned		
Private X-rays, scans		
Patient's own medication		
Walking aids		
Advice		
Patient able to state signs / symptoms requiring presentation; temp / feels feverish / pain and or problems with wounds		
Post-op education and precautions stated		
Referrals		
To _____ booked		
Clip remover and Anti-embolic therapies given to patient		
Follow-up Appointment		
Made and appointment card issued		
Will be posted		
Patient will make their own booking		
Not Required		
Support Services Information provided re support services		
PHYSIOTHERAPY		
◆Independent and safe transfers / mobility		
◆Home exercise programme provided		
Active Flex to ___, Ext Lack___, SLR Y/N with ____ lag		
Aid_____assist_____, distance_____, m, Stairs____		
TUG: _____Sec. Standing valgus / varus : _____		
Physiotherapy referral to :-		
By Whom_____ Date_____		
Comments		

Appendix 8 Surgical procedure standardisation.

Subvastus and Medial Parapatellar Surgical Procedure

Perform five Subvastus with Dr Dodsworth and sign declaration before commencing recruitment of participants
(Investigating surgeon to be present for all participants)

Subvastus Surgical Protocol

1. Tourniquet on but not inflated
2. Knee flexed for skin incision and incision of inferior aspect of capsule. Subvastus then dissected with knee flexed or extended
3. Patella not to be everted, but subluxed laterally
4. Patella not denervated
5. Tourniquet up for duration of cementing only
6. Redivac™ exits laterally avoiding vastus lateralis if possible. Removed Day 1
7. Incision closure in flexion at approximately 90 degrees
    i. Strategic interrupted sutures (superior/ inferior pole patella)
    ii. Then continuous capsular

Medial Parapatellar Surgical Protocol

1. Tourniquet on but not inflated
2. Knee flexed
3. Medial parapatellar incision extending 6-7cm above proximal pole of the patella
4. Extend incision inferiorly to medial aspect tibial tubercle
5. Evert patella, if required, for the duration of the surgery
6. Tourniquet up for duration of cementing only
7. Redivac™ drain exits laterally avoiding vastus lateralis if possible. Removed Day 1
8. Incision closure in flexion at approximately 90 degrees
    i. Strategic interrupted sutures (superior/ inferior pole patella)
    ii. Then continuous capsular

<u>Theatre Research Protocols</u>

Recruitment

1. Collect your pink recruitment kit before each clinic
2. Check patient meets inclusion/exclusion criteria
3. Issue Patient Information Sheet
4. Obtain signatures on:
    i. Study Consent Form
    ii. Photograph Consent Form
5. Place patient sticker on referral form
6. For Participant who would like to go away and think:

    Record their name and phone number on Study Consent Form in kit – make follow-up phone call the following week
7. Send Participant to Allied Health Reception (with all pink forms signed appropriately) for registration into the study.

Recruitment from waiting list

1. Obtain list of patients on waiting list from Nurse Case manager
2. Surgeon to Telephone patients
3. Explain study over the phone
4. Determine patients desire to participate in the study
5. Book appointment with patient to establish eligibility
6. Follow usual recruitment procedure above

Operating Theatre

Establish the randomised surgical approach before entering theatre:

- ☐ Collect PDA from the Large dangerous drugs cupboard in Recovery Room before the operation.
- ☐ Turn On PDA (top right corner)
- ☐ Remove stylus (top right corner)
- ☐ Tap Start (top left of screen)
- ☐ SMPPS (i.e. Subvastus Medial Para Patella Study)
- ☐ …. Wait… it can take a moment too open
- ☐ Enter Password – "cat" – tap login
- ☐ Tap "Intra-Operative Data'
- ☐ Enter UR and identify the Surgical Approach
    - Group allocation will be revealed when the patient's data is opened and it will be

to either SVa or MPa

Collect all data and photographs as trained – Tap Accept

PDA Data Entry

Including photographs — Flexion (hanging with hip ~90º)

Extension (hanging with heel supported)

(Greater Trochanter, LFC and Lat Mal visible)

Comfeel Dressing applied in flexion	Left intact 48 hrs then change if excessive ooze
Blinding of Physiotherapists	Place original Operation Report in Study Envelope-place envelope in chart. Place copy in chart (Black Out the Surgical Approach on the copy so it cannot be identified by the Physiotherapist on the ward)

Return PDA to Large DD cupboard in Recovery

Pain Relief	Discuss preop with the anaesthetist that there are to be no epidurals or femoral nerve blocks on the ward (due to impact on early quads function and mobility) PCA removed Day two post-operatively Drain Removed Day one (after Active Flexion)
IDC	Removed Day 2
Antibiotic prophylaxis	1. Cephazolin IV 1g & gentamicin 3mg/kg on induction 2. Cephazolin IV 1g TDS for 24hrs & single dose Gentamicin at 24hrs
TEDS	Bilateral below knee (nil else) for six weeks
Oedema management	Tubigrip after Day one flexion Cold therapy. Elevation as able
Inpatient anticoagulation	Surgeon Specific
Discharge Criteria	Safe and Comfortable ~90° Flexion aim <5º Extension Lack aim <5º Extension Lag on SLR Independently mobile on appropriate aid
Clip removal	10-14 Days at GP or at QEII

Appendix 9 Physiotherapy post-operative guidelines

Total Knee Replacement

Guidelines for Physiotherapy Management

Day one Post-operatively:

- Respiratory and circulatory assessment and exercises
- SLR to be commenced as able, bed mobility
- May mobilise FWB with a walking aid a short distance if appropriate (i.e. consider BP, Hb, nausea etc)
- *Richard's splints* – may be used: a) overnight to maintain extension
  b) to mobilise if insufficient quads control
  c) on unstable knee as determined by treating consultant
- *Day one knee flexion* – can be performed in a chair or on the edge of the bed (lowered). This should be performed whilst the drain is in-situ (if drain used). The patient's foot should be supported on a skateboard or a powder board. The knee dressings can be de-bulked and the patient 'actively' flexes the knee to 80-90° (without being over-zealous). The leg at no time should 'dangle' as quadriceps inhibition will increase pain and hinder the flexion. Once completed the patient is assisted back into bed, the knee slightly elevated and a Lumark Cold Compression Device applied. Nursing staff are then notified for removal of the drain 1-2 hours later, usually around midday. Sitting time on day one is limited to treatment time only unless the patient has respiratory compromise.

  Note: assisted knee flexion may be performed with the patient supine if they are unable to sit up due to dizziness (e.g. low Hb/BP etc)
- All patients require a double layer of tubigrip on their operated limb for two weeks
- Bed exercises may include inner range quadriceps, gentle knee flexion with powder board and straight leg raise (SLR).

Day 2:

- Continue exercises as above, focusing on SLR and IRQ.
- Mobilise the patient with a rollator or progress to hopper/wheeled walker as appropriate
- Active knee flexion can be continued in a chair. It may be appropriate to limit the flexion to approximately 70-75° due to the potential for over doing the exercises and increasing the post-operative swelling. Treatment should be followed by elevation and cold compression therapy repeated as required. Sitting time limited to manage swelling.

Day three → discharge:

- Progress exercise as above.
- Progress knee flex to 90° and beyond as able & commence standing exercises (e.g. mini-squats, standing flexion, heel raises, stair lunges and knee extension hangs).
- Progress quads exercises to independent SLR and mini squats (if FWB), and balance exercises.
- Mobility may be progressed to hopper frame, four wheeled walker or 2x sticks.
- Length of Stay usually 4-5 days.

Post discharge follow-up:

- All local patients are encouraged (if indicated) to attend the post-operative knee class. Some may only need to attend 2-3 times.
- Patients who require follow up and have transport difficulties may be offered post-acute funded physiotherapy home visits, but only in liaison with discharge facilitator (#6112).

Unicompartmental Knee Replacement (UKR):

- Similar guidelines as above - should progress much quicker and aim D/C day 2-4.

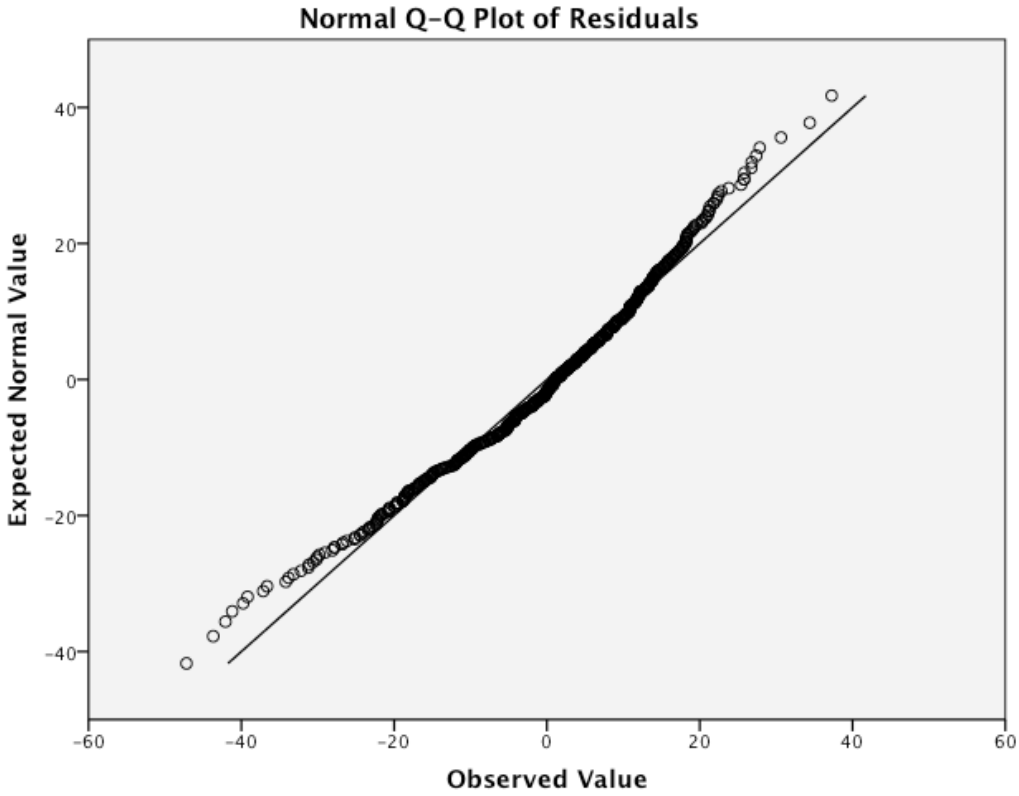
General Aims of Treatment:

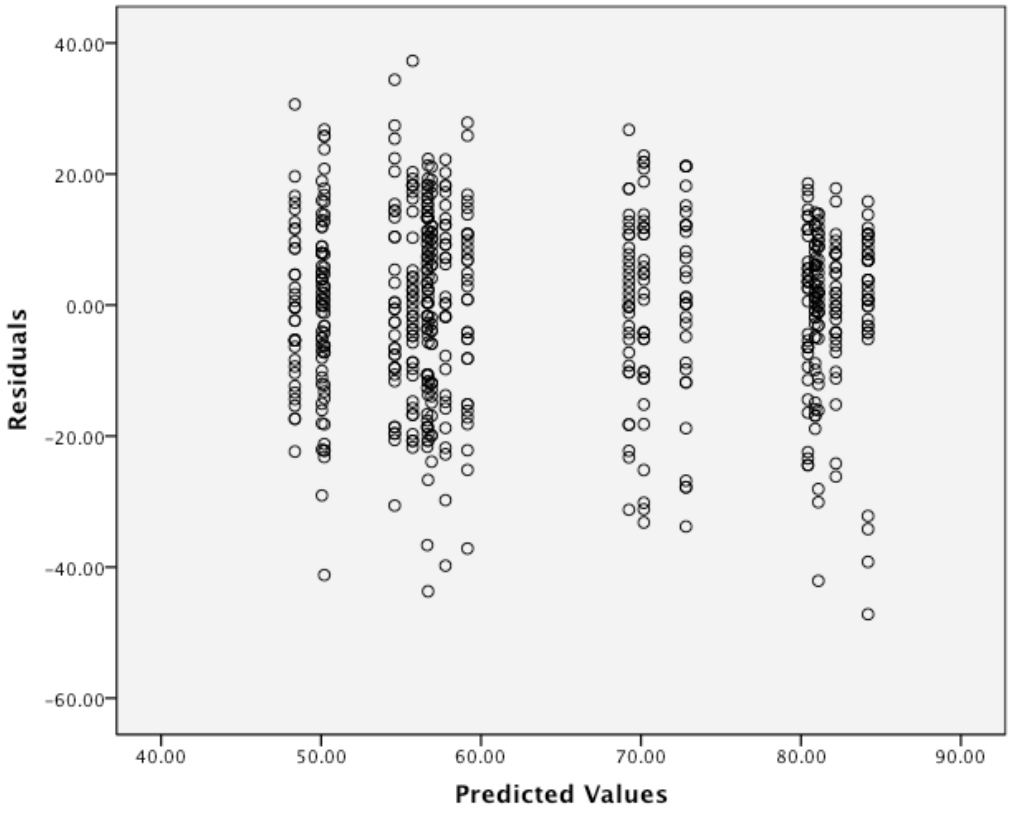
- All inpatient treatment should be aimed at assisting patients to become independent in their exercise programme. They should refer to their exercise handout regularly.
- CPM may be considered if daily flexion goals are not being achieved.
- Discharge occurs when the patient is safe and comfortable.

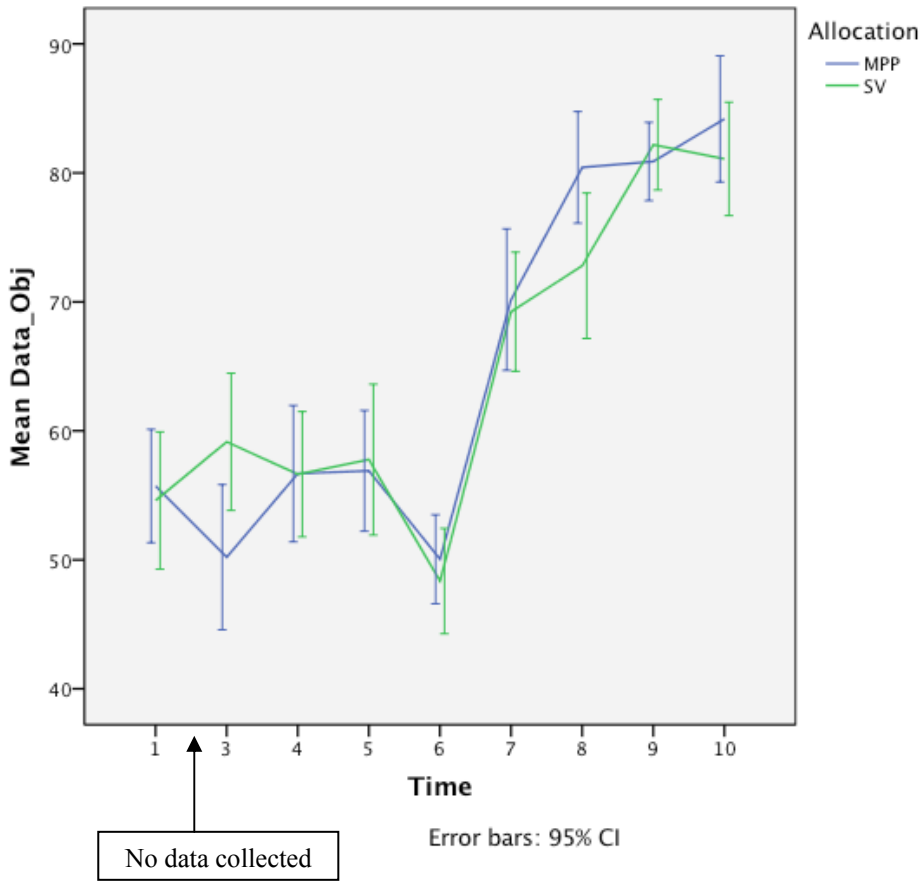
Appendix 10 Linear mixed modelling

Normal Q-Q plots of residuals, scatterplots of residuals and predicted values, and line graphs of means

American Knee Society Score - Objective



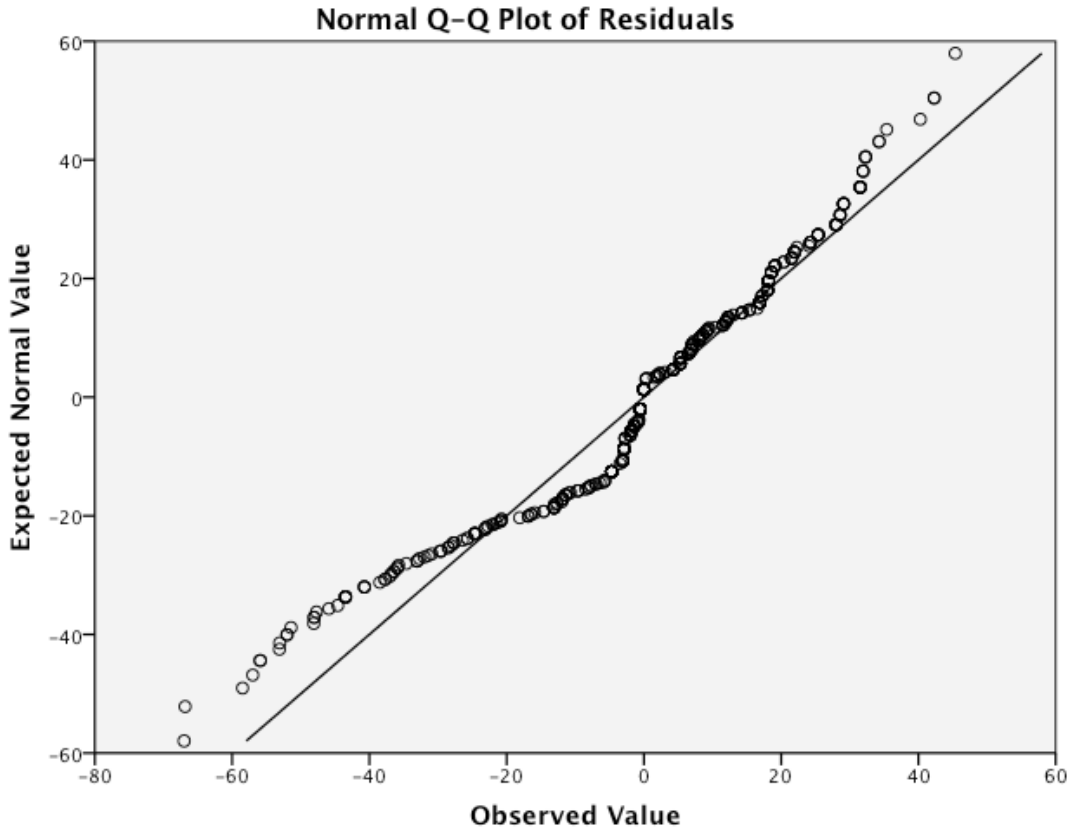


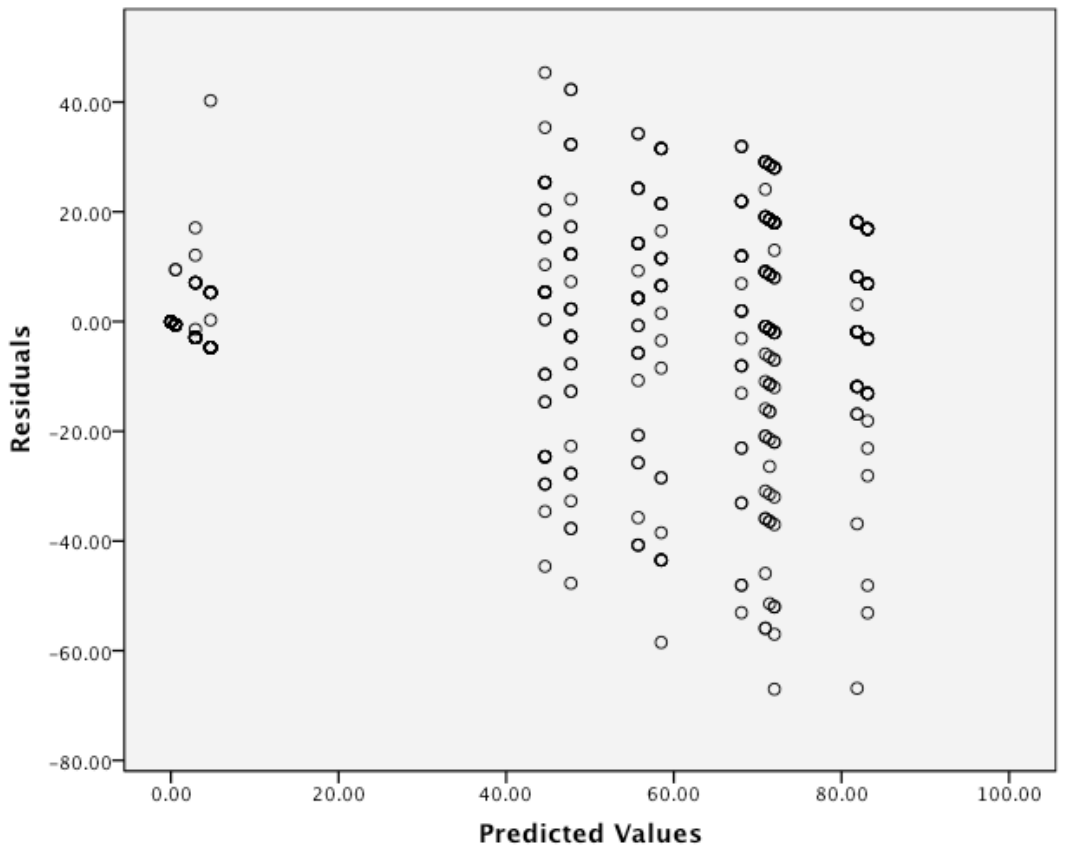


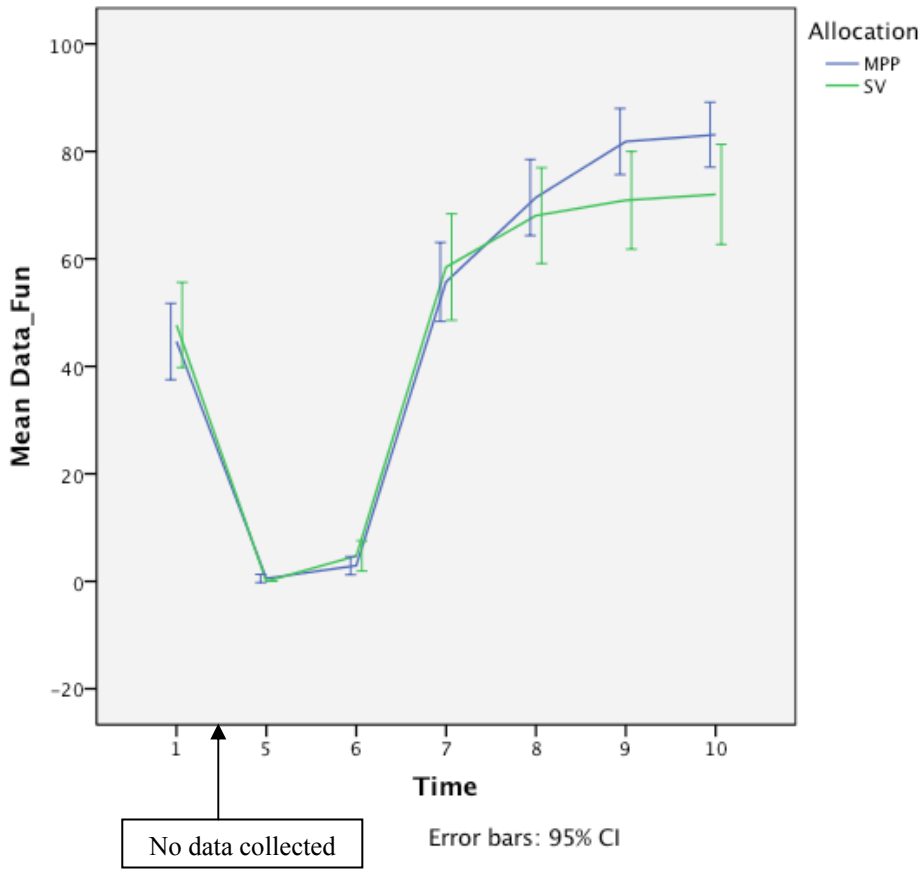
Legend:

Time 1	Pre-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

American Knee Society Score - Functional



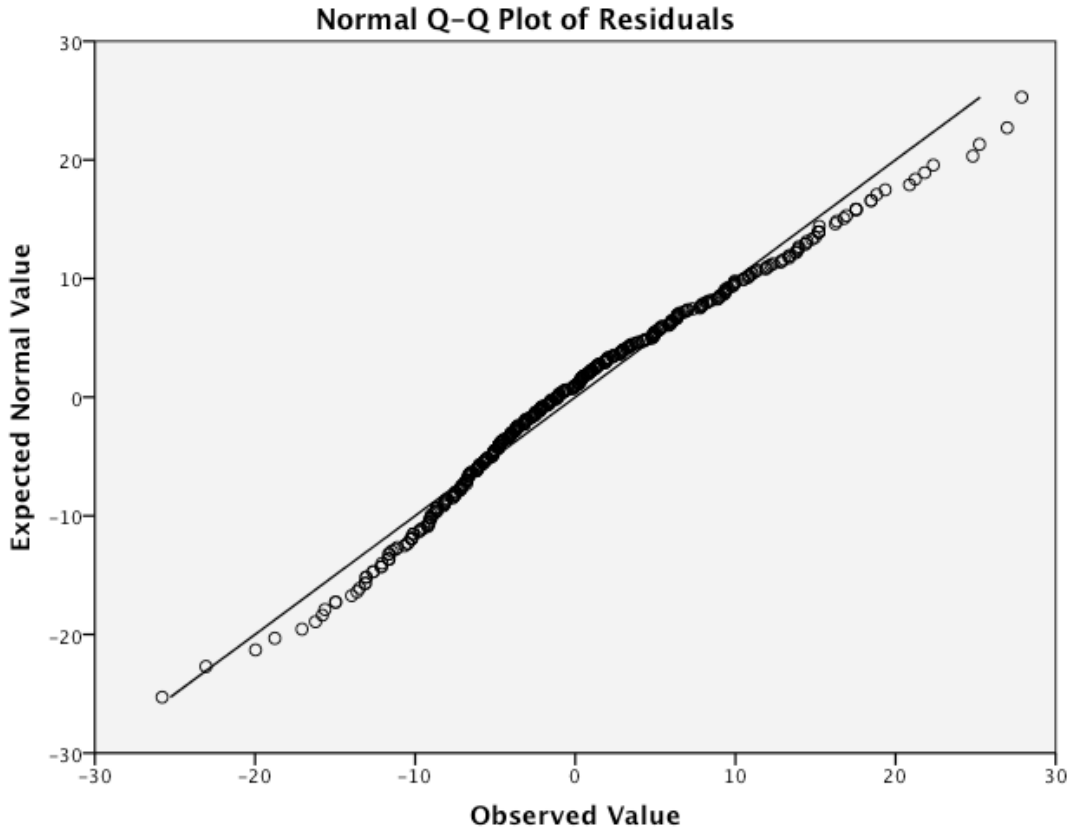


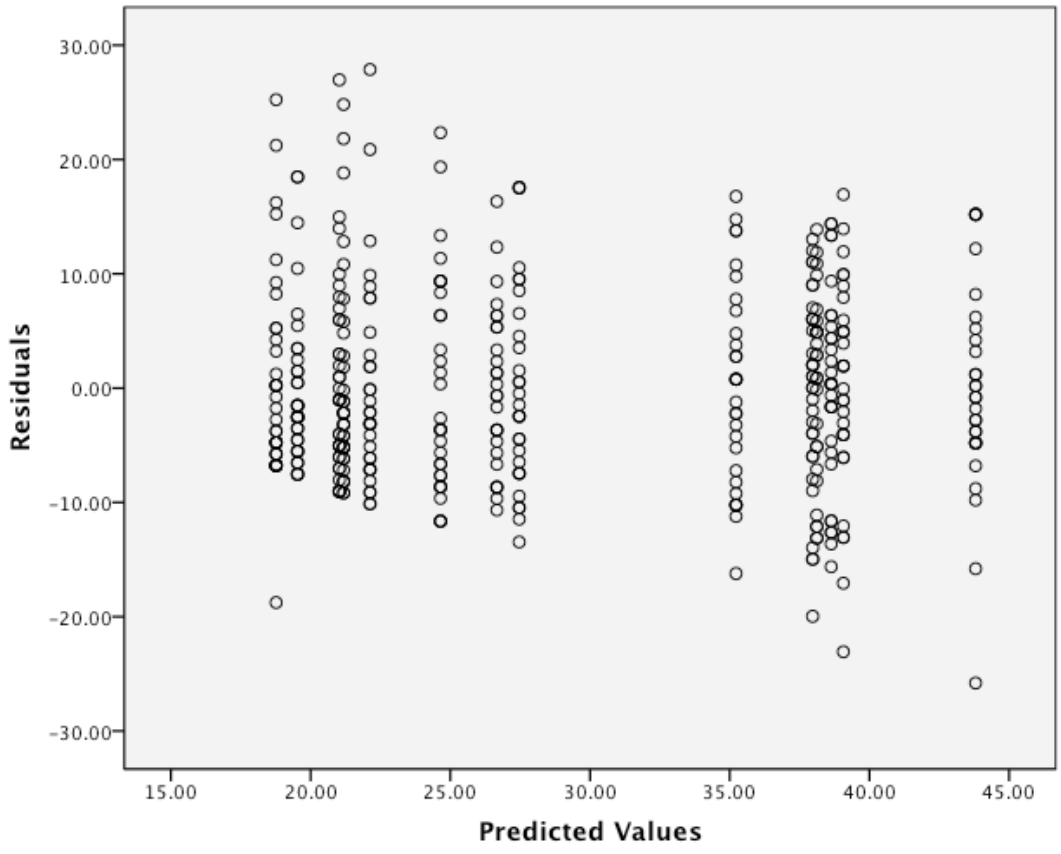


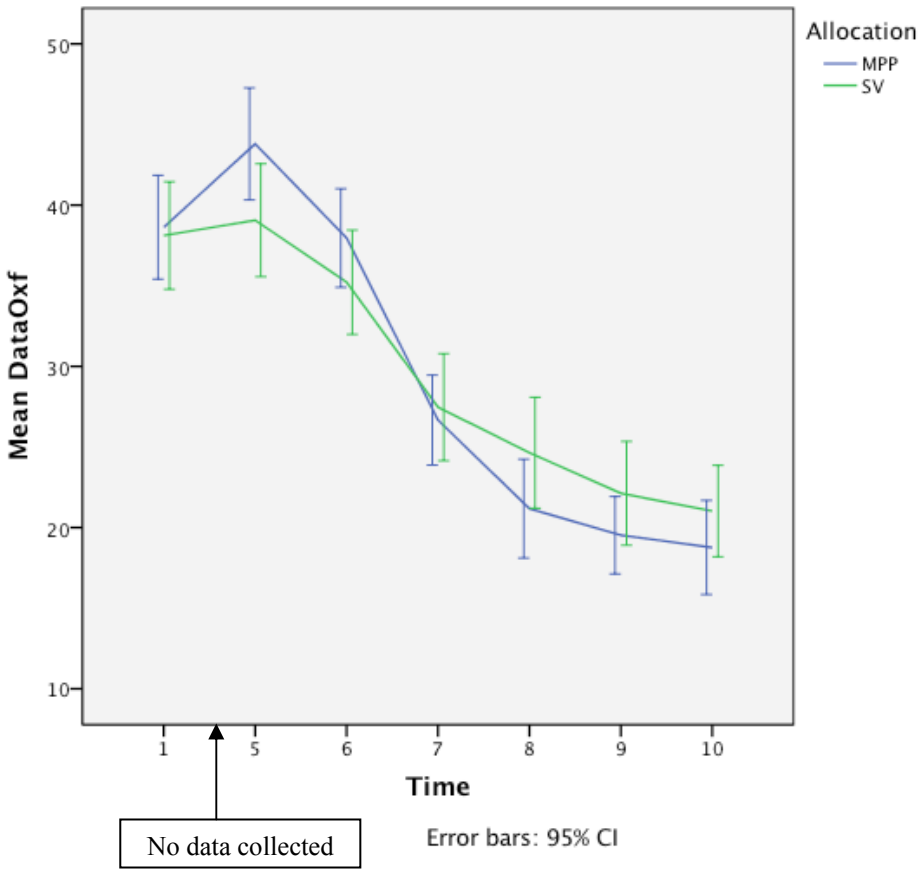
Legend:

Time 1	Pre-operative
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Oxford Knee Score



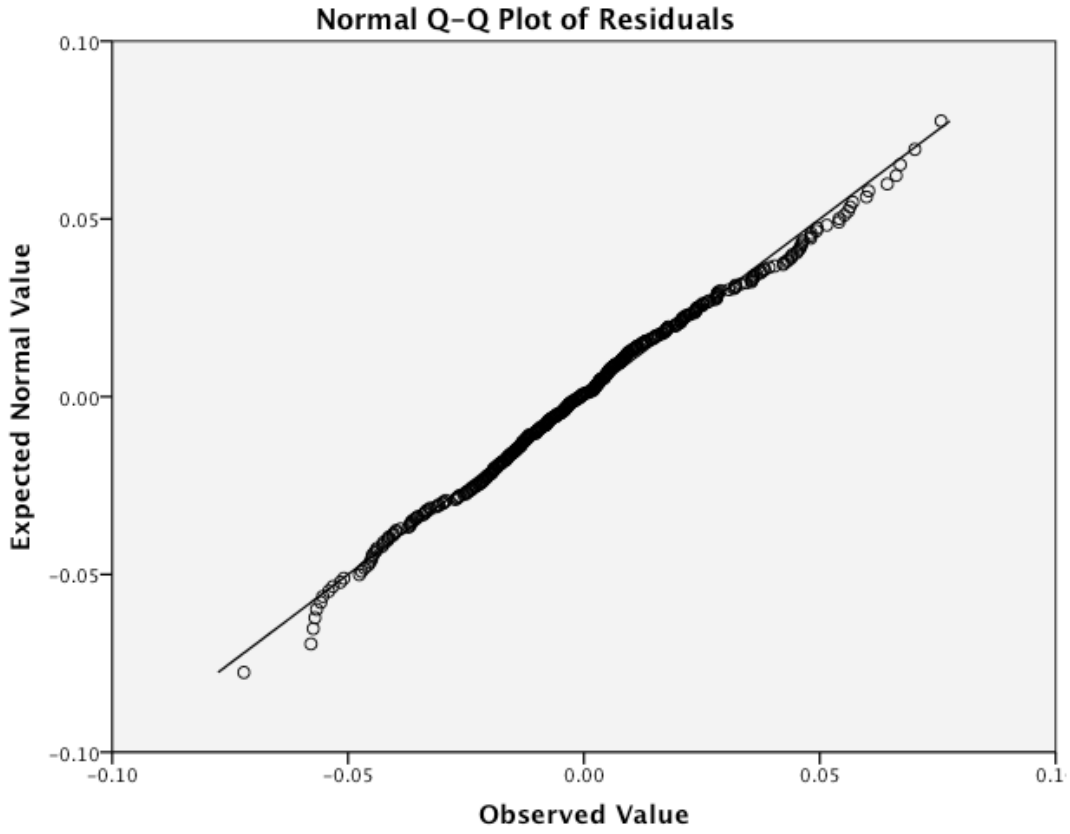


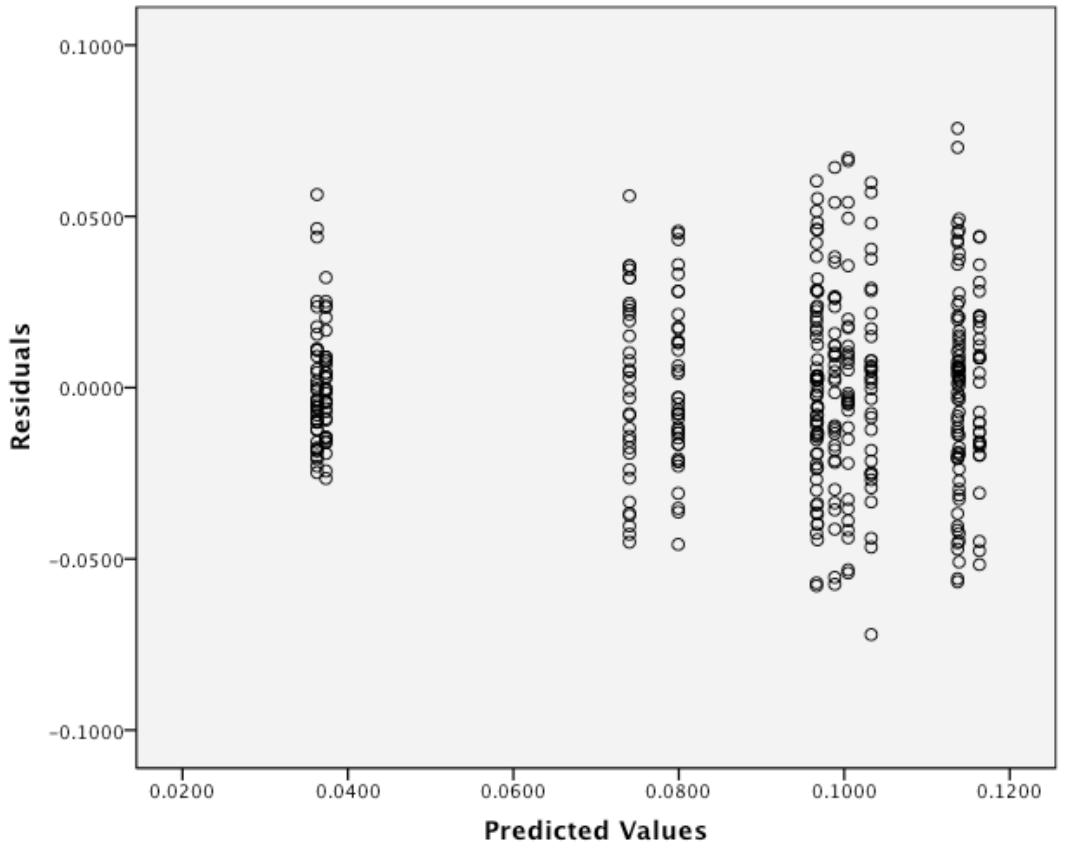


Legend:

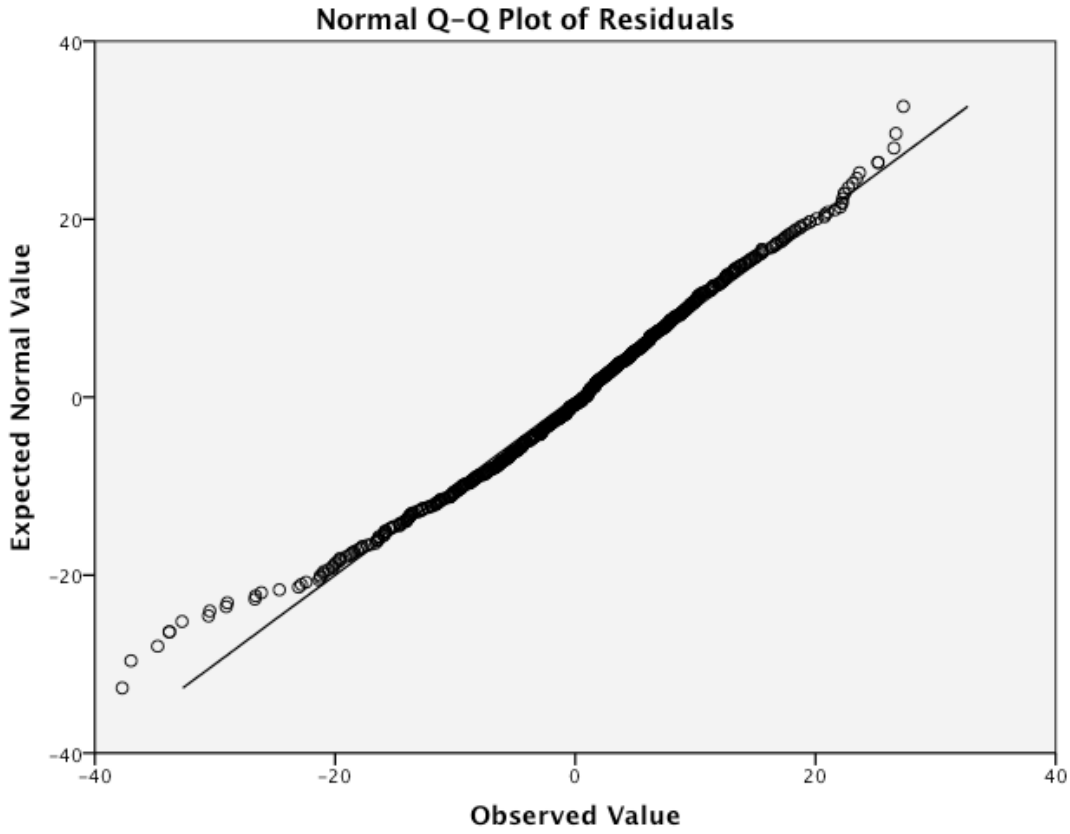
Time 1	Pre-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Timed Up and Go test (Transformed data)





Flexion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Expected Normal Value
Observed Value
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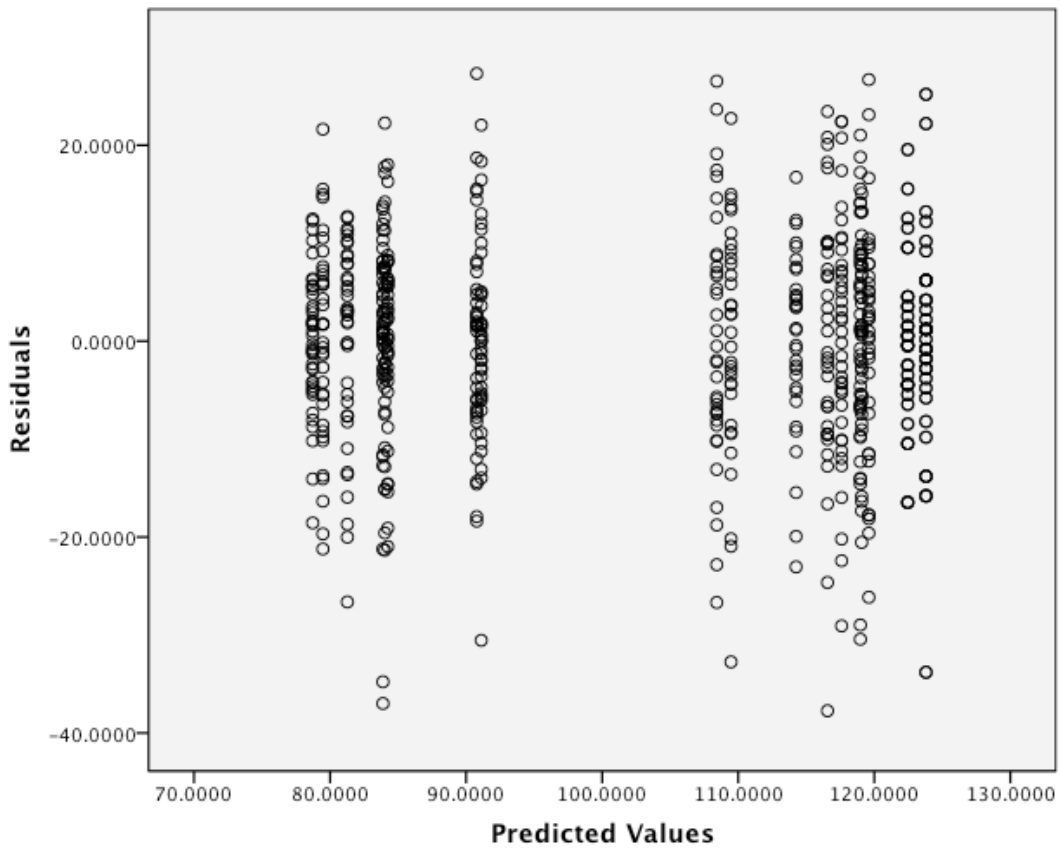
20
0
-20
-40
-40
-20
0
20
40


Residuals
Predicted Values
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-20.0000
-40.0000
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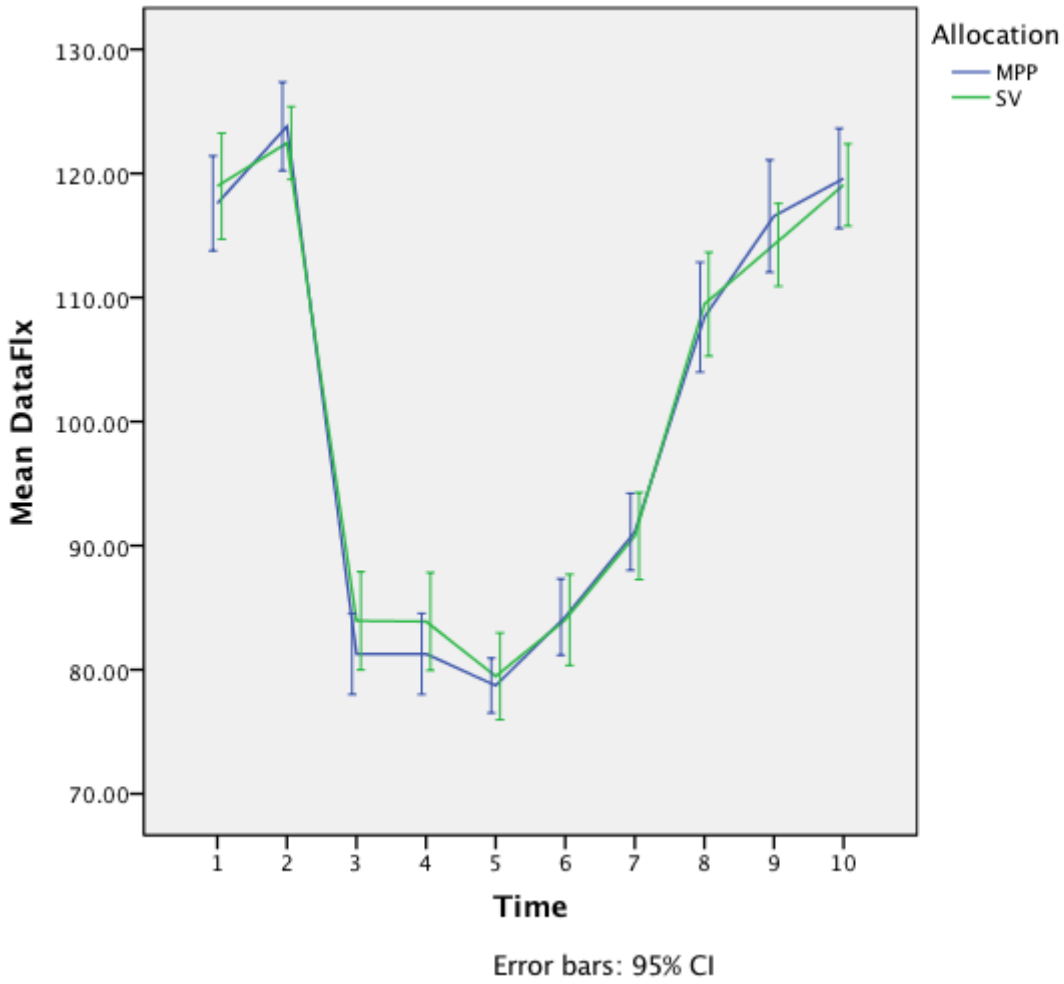
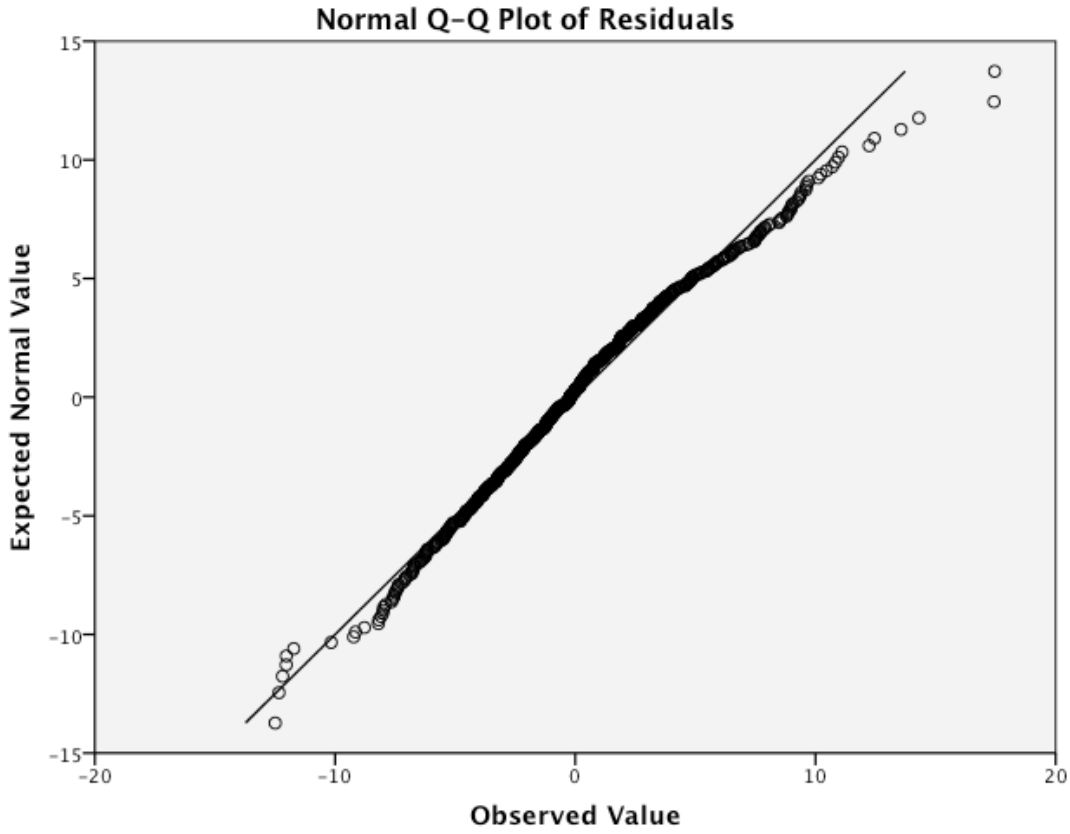
80.0000
90.0000
100.0000
110.0000
120.0000
130.0000



Legend:

Time 1	Pre-operative
Time 2	Intra-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Extension


Normal Q-Q Plot of Residuals
Expected Normal Value
Observed Value
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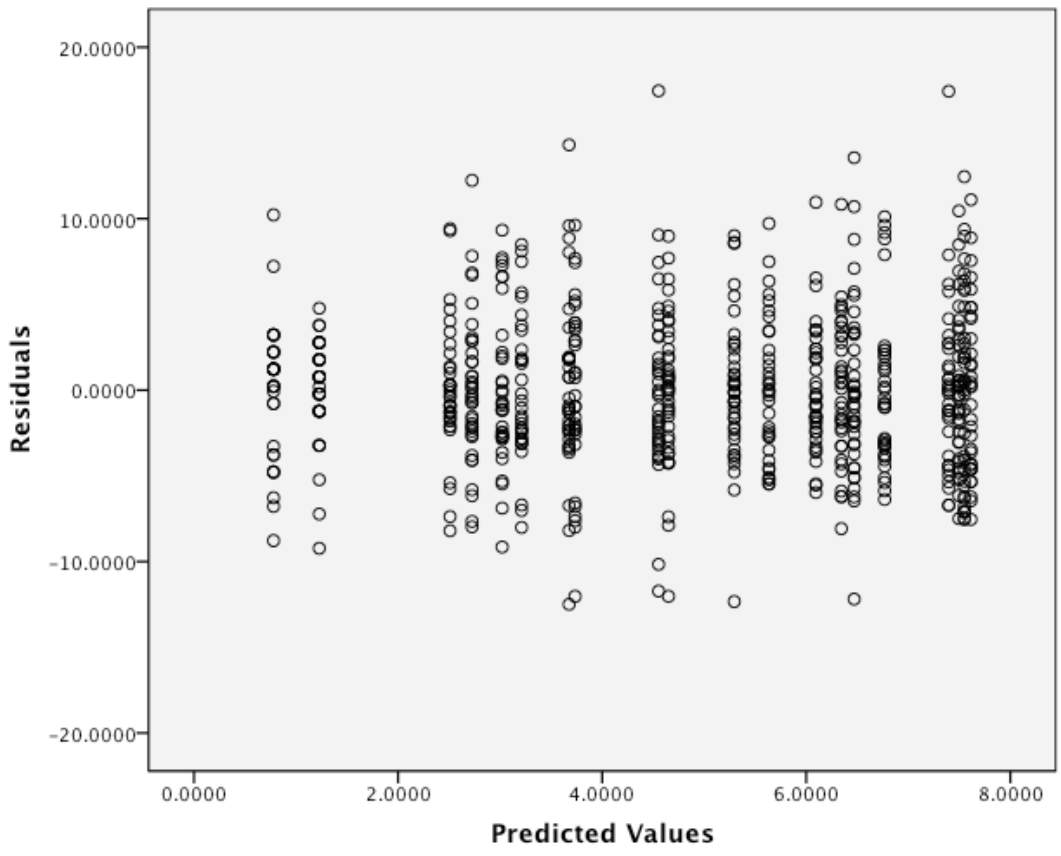
10
5
0
-5
-10
-15
-20
-10
0
10
20


Residuals
Predicted Values
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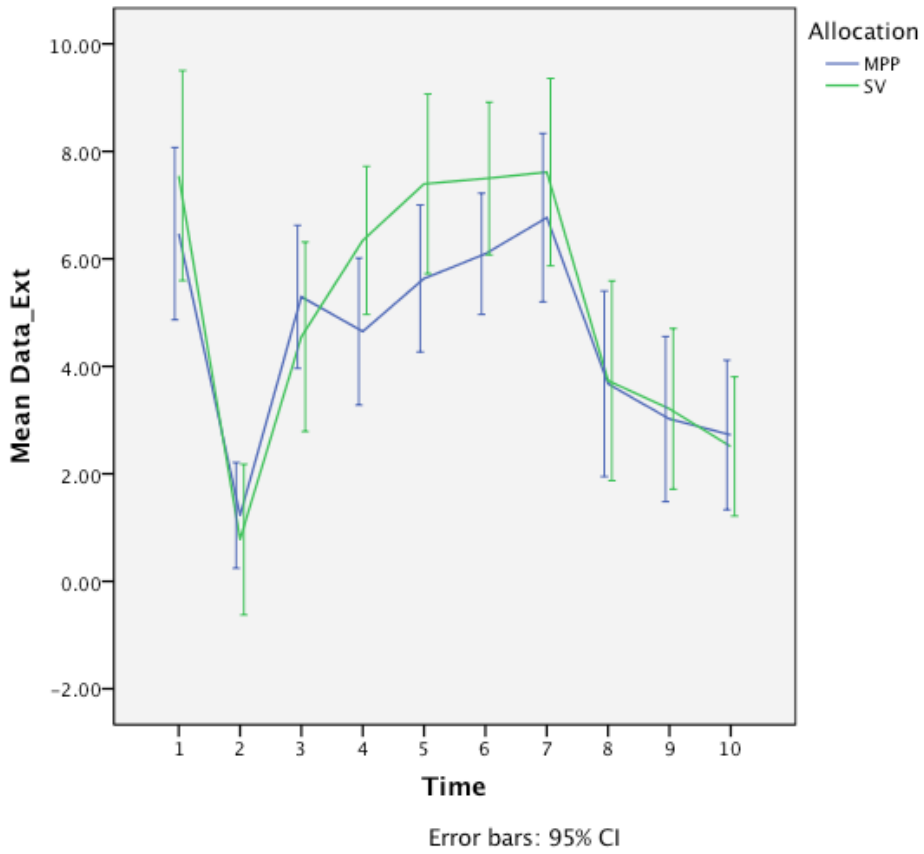
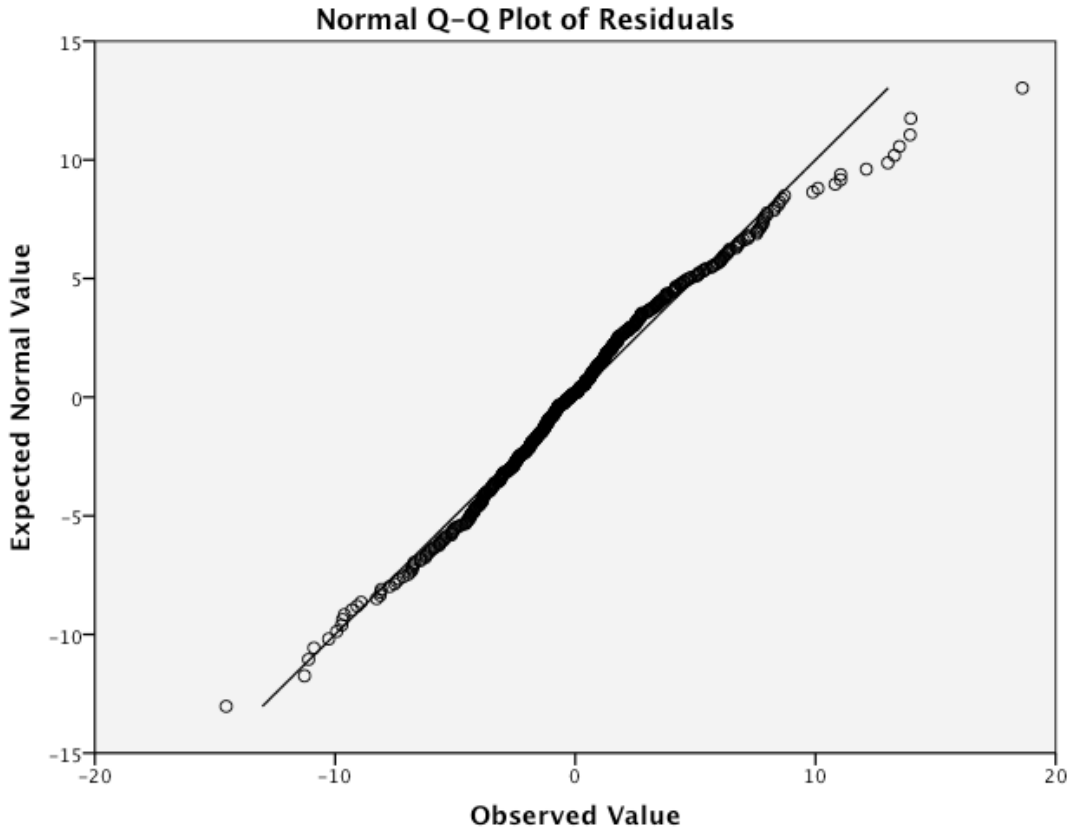
-20.0000
0.0000
2.0000
4.0000
6.0000
8.0000

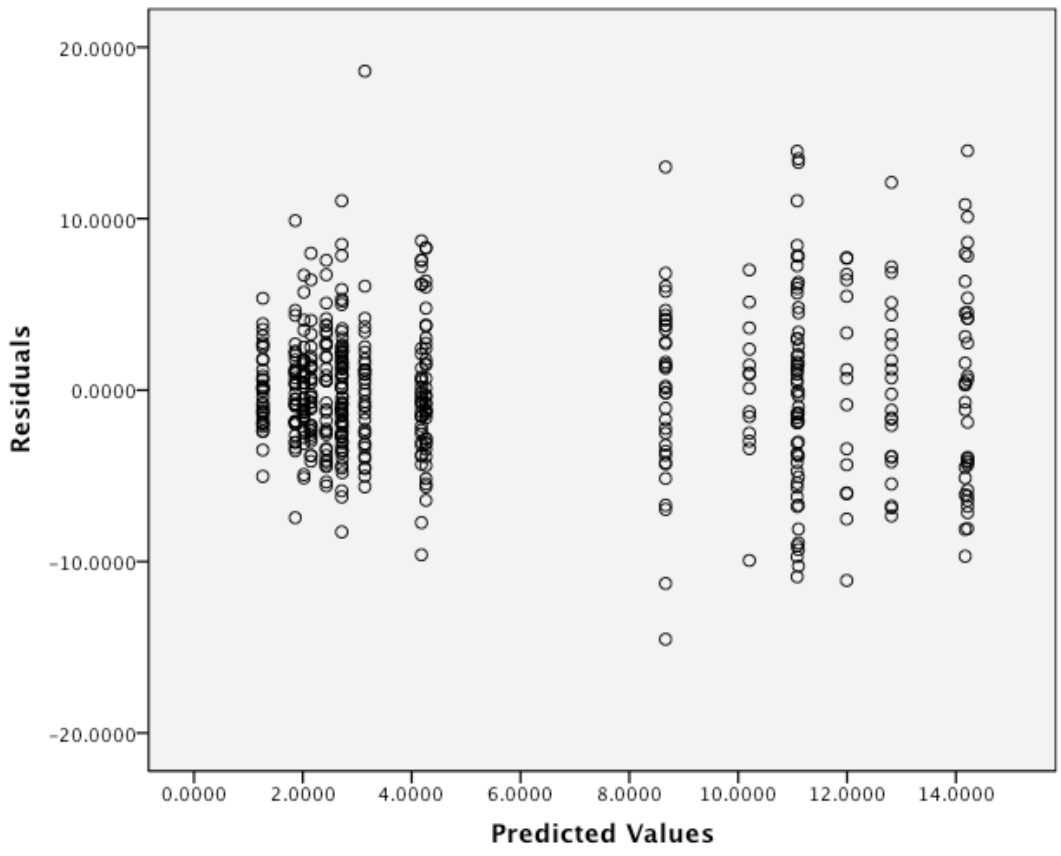


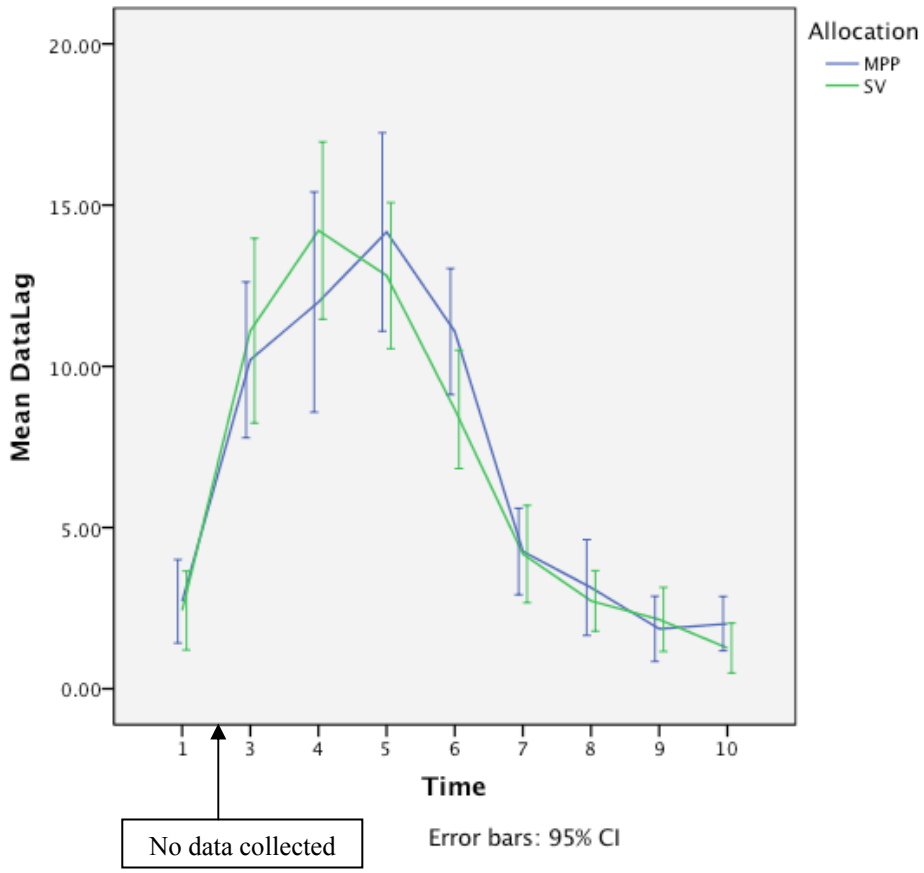
Legend:

Time 1	Pre-operative
Time 2	Intra-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Quadriceps lag on straight leg raise



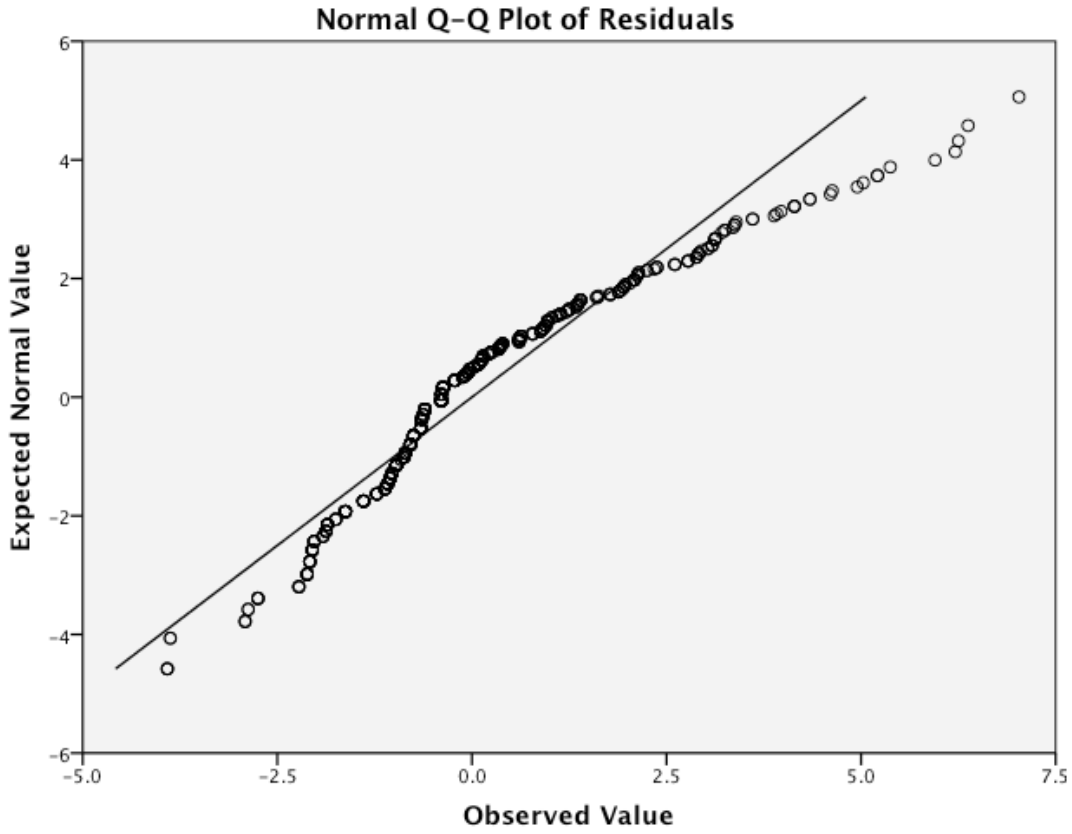




Legend:

Time 1	Pre-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Knee pain


Normal Q-Q Plot of Residuals
Expected Normal Value
Observed Value
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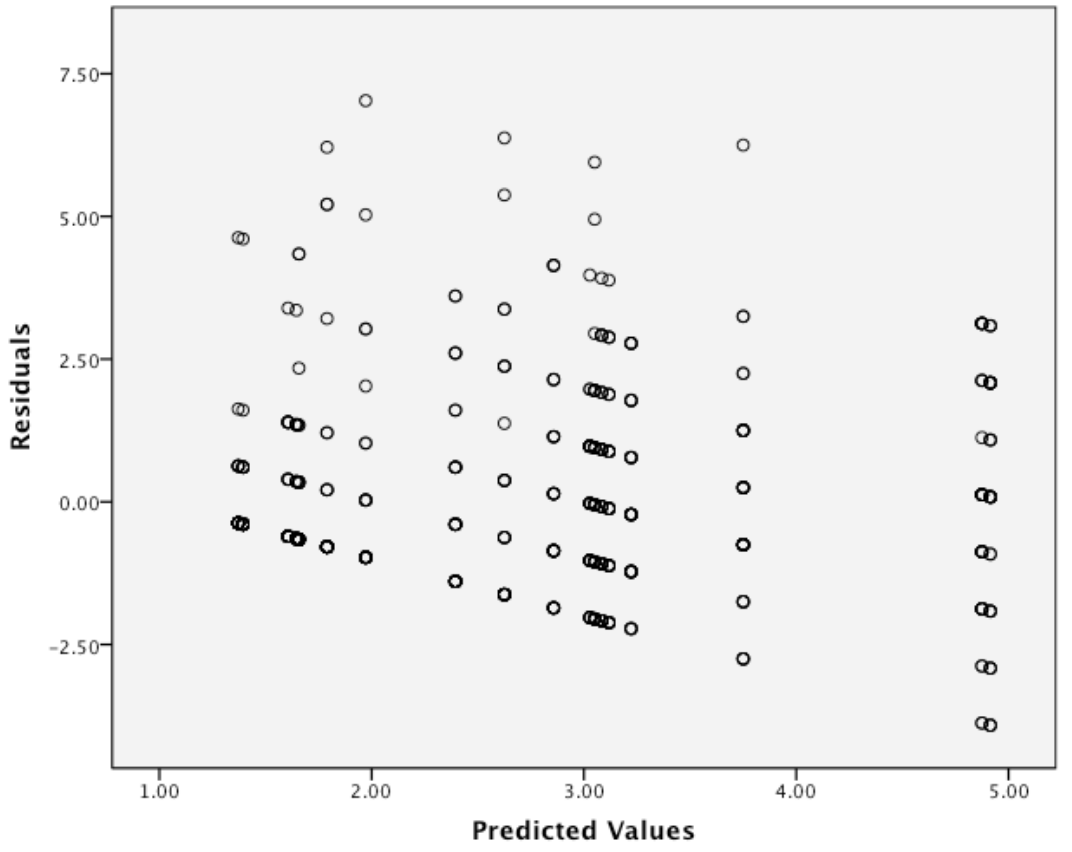
2
0
-2
-4
-6
-5.0
-2.5
0.0
2.5
5.0
7.5


Residuals
Predicted Values
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0.00
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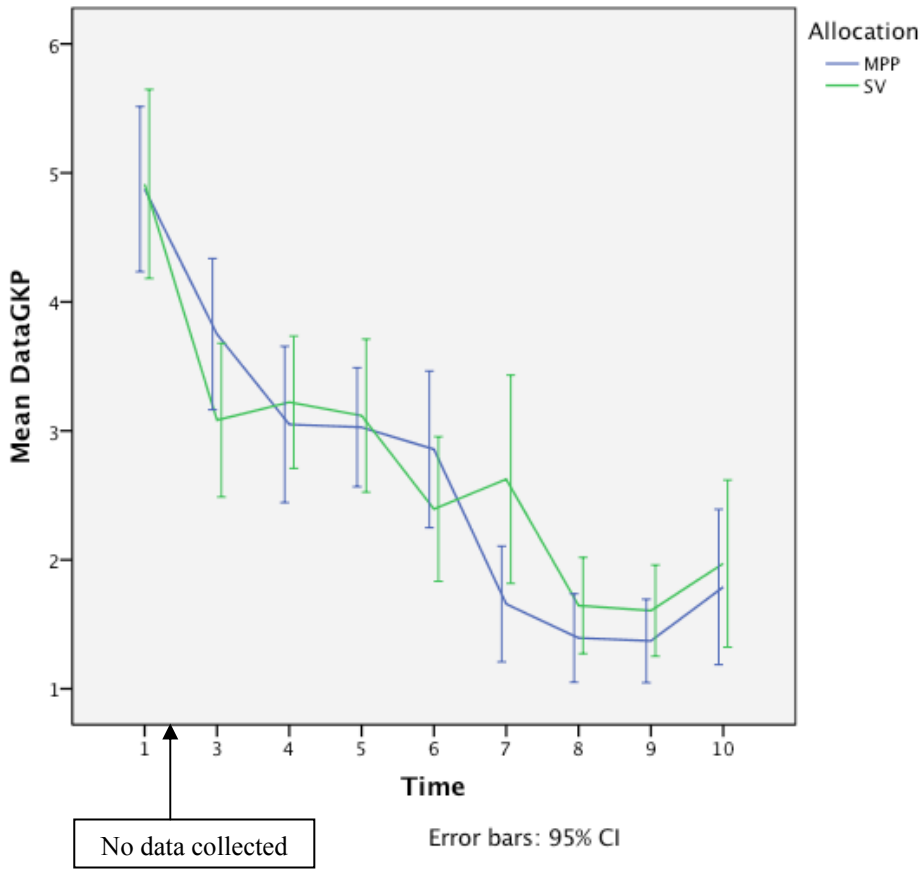
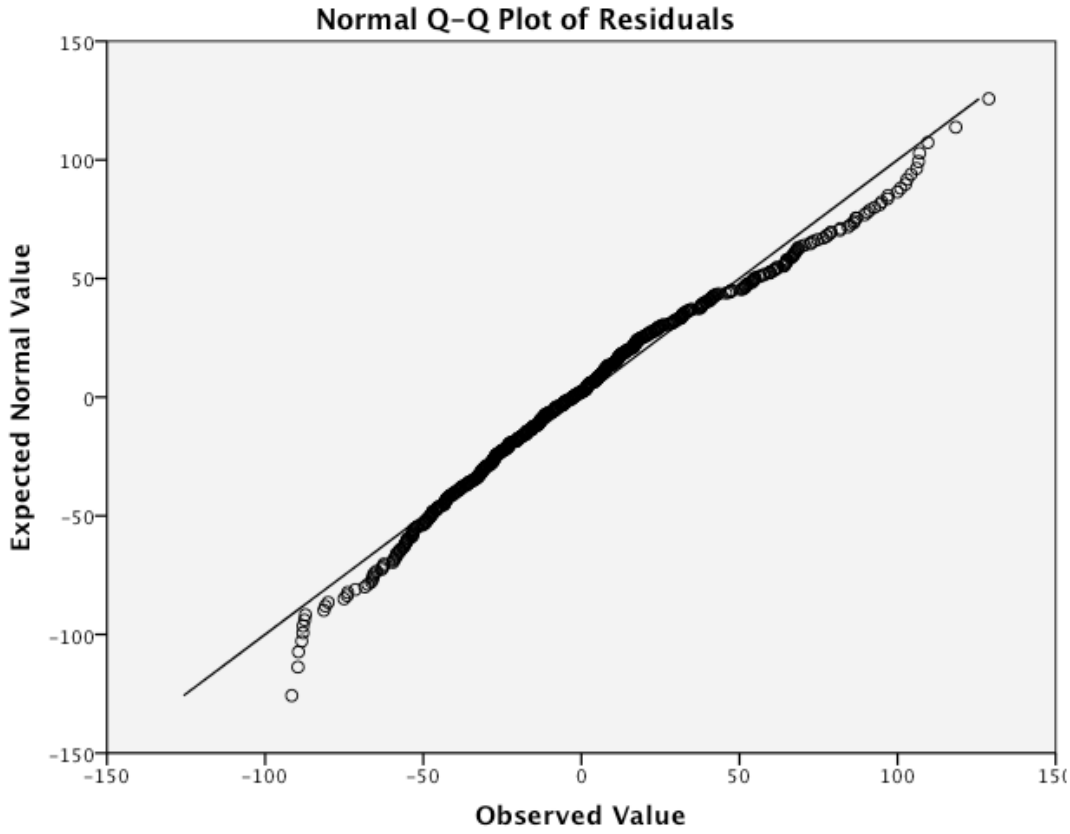
1.00
2.00
3.00
4.00
5.00



Legend:

Time 1	Pre-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Knee girth


Normal Q-Q Plot of Residuals
Expected Normal Value
Observed Value
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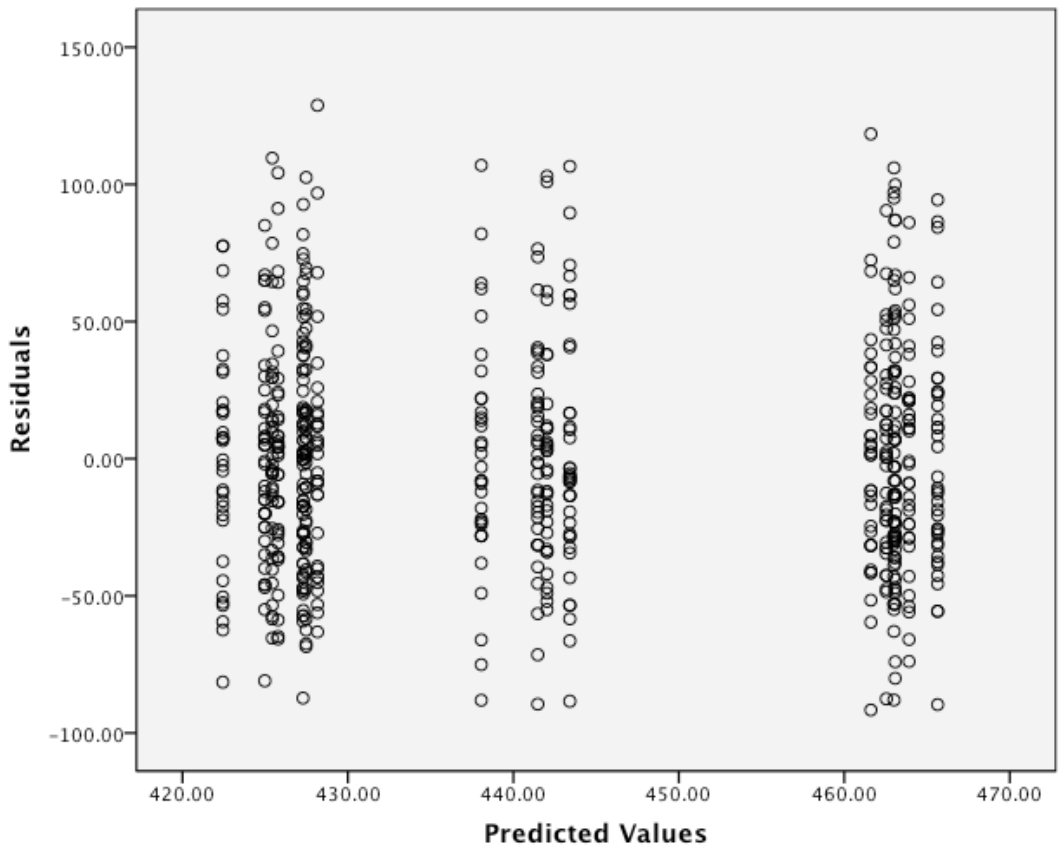
100
50
0
-50
-100
-150


Residuals
Predicted Values
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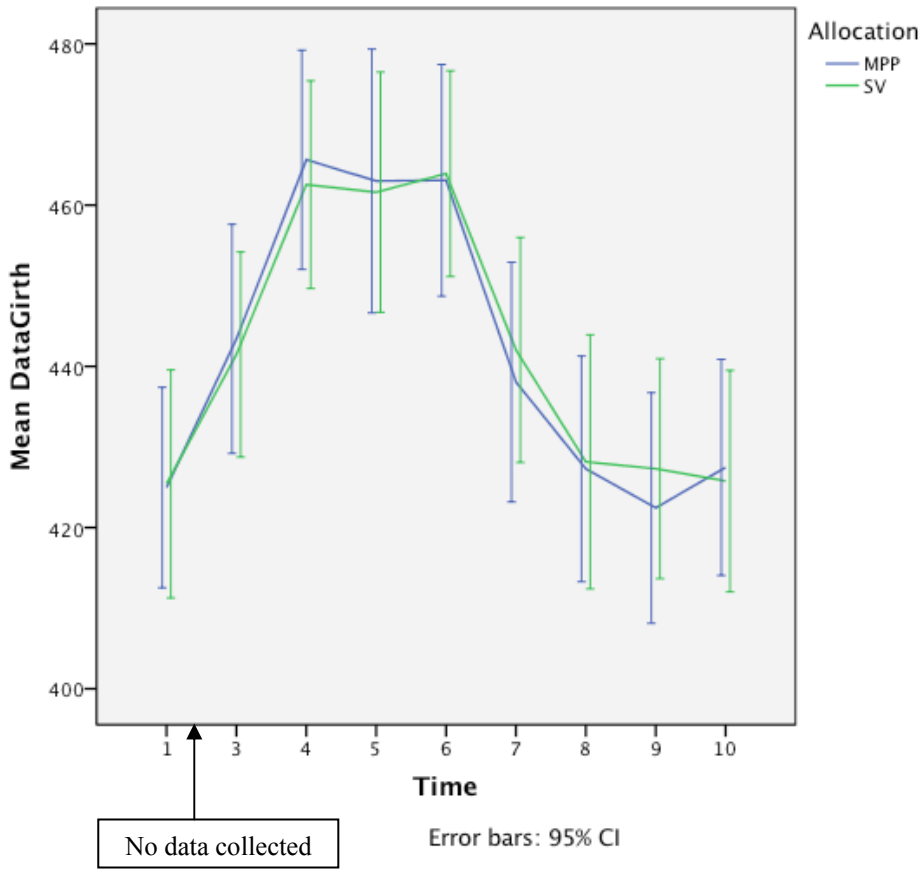
-100.00
420.00
430.00
440.00
450.00
460.00
470.00

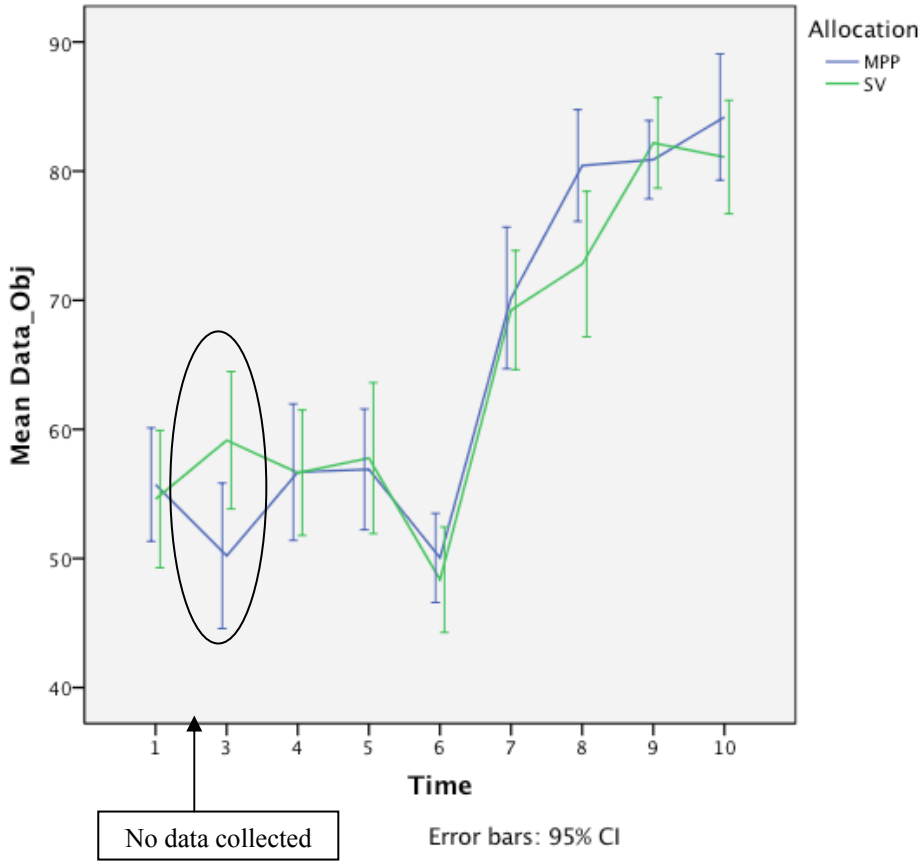


Legend:

Time 1	Pre-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Appendix 11 Line graph: AKSS Objective Day one Score

Demonstrating significantly better scores for the subvastus approach on Day 1.

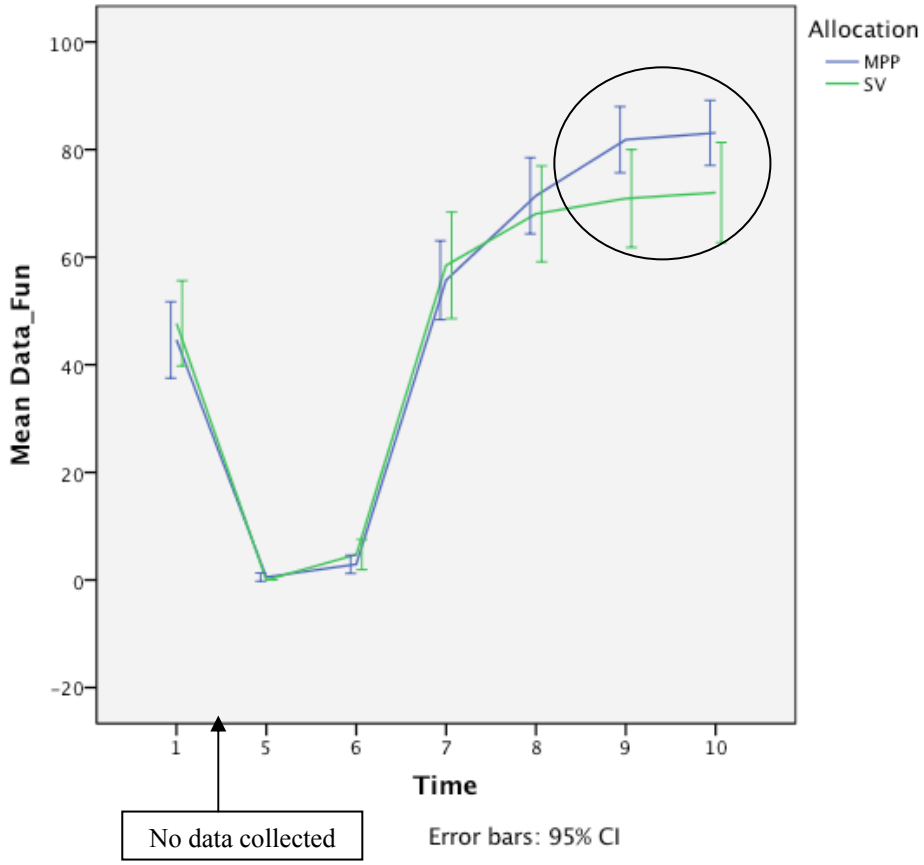


Legend:

Time 1	Pre-operative
Time 3	Day 1
Time 4	Day 2
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Appendix 12 Line graph: AKSS Functional Score 12 and 18 months

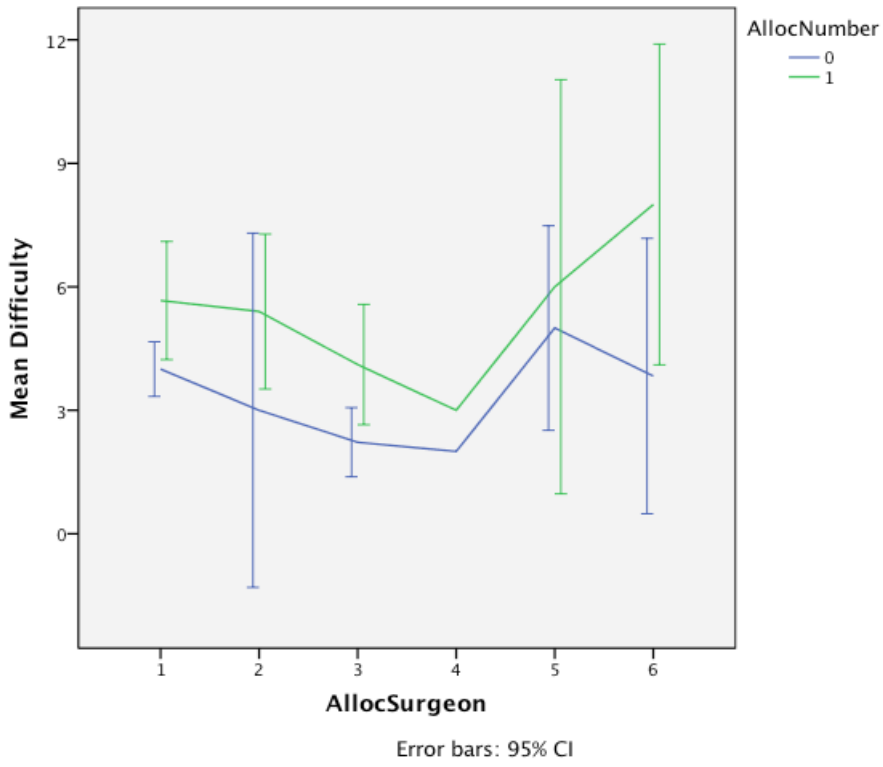
Demonstrating significantly better scores for the subvastus approach.

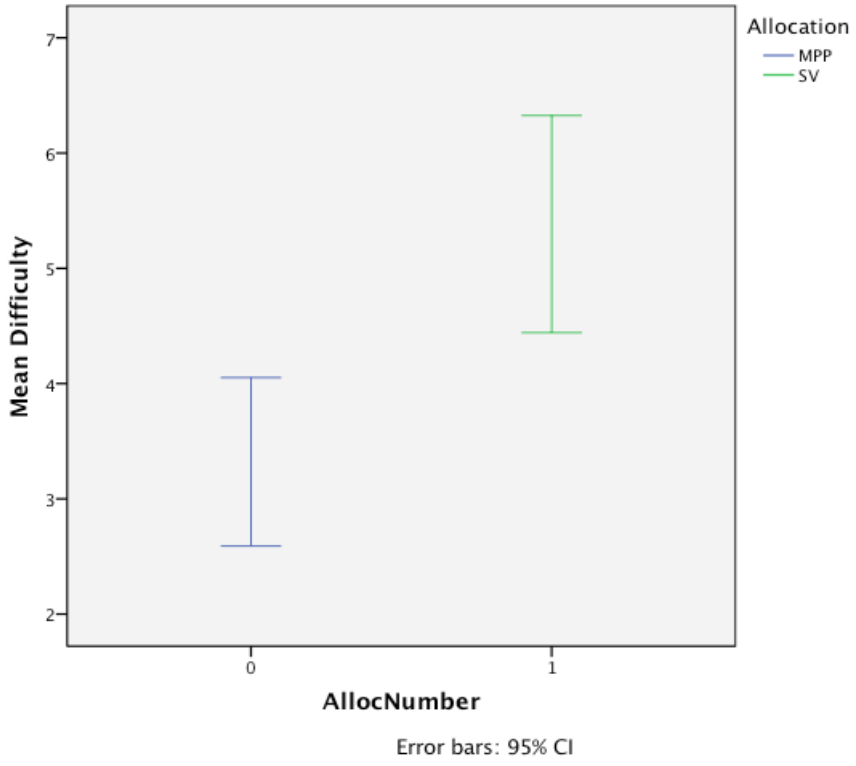


Time 1	Pre-operative
Time 5	Day 3
Time 6	Discharge
Time 7	Week 6
Time 8	Month 6
Time 9	Month 12
Time 10	Month 18

Appendix 13 Surgeon perceived level of difficulty

Demonstrating that surgeons perceived the subvastus approach to be a more difficult operation.





Appendix 14 Ethics approval correspondence – Patellar vascularity

Michael Bourke
Senior Physiotherapist – Orthopaedics
QEII Jubilee Hospital
PMB 2 Acacia Ridge
Brisbane 4110
Ph (07)3275 6173
Fax (07)3275 6419
Email michael_bourke@health.qld.gov.au

Queensland Government

Queensland Health

Anne Walsh
Ethics Secretariat
Princess Alexandra Hospital
Woollongabba
Ph (07)3240 5856
Fax (07)3240 7667
Email pah_ethics_research@health.qld.gov.au

19 October, 2007

Dear Ms Walsh and members of PAH HREC,

RE: Ethics Amendment for
An evaluation of the clinical outcomes of the subvastus versus the medial parapatella approach to total knee replacement *2005/190*

A bone scan for patella vascularity is being conducted at 18 months post operatively. The first scan is due on 21/12/2007. Since our original ethics application, new scanning technology has become available to enable better assessment of patella vascularity. We are advised it carries no greater risk than a conventional bone scan. We seek your approval to progress with the process outlined below.

"We propose that the bone scan will be performed on a GE Hawkeye camera which is a combined SPECT (single photon emission computed tomography) /CT system. This system incorporates a dual-head gamma camera with SPECT capability for nuclear scanning together with an integrated low dose, four 5mm slice thickness CT for anatomical localisation. The helical CT operates at 140 kV and 2.5 mA. The x-ray tube and detector array rotate together at 2.6 rpm.

The effective radiation dose for a bone scan in an adult receiving 800 MBq of Tc-99m methylene diphosphonate for bone scanning is 5 mSv. [1]

The CT of the GE Hawkeye camera operates at 35 mAs which is much lower compared to conventional diagnostic CT which typically operates between 200 to 350 mAs. The effective radiation dose for a CT of the knees on the GE Hawkeye is very low due to the low mAs and the knees being relatively non-radiosensitive anatomy. It is calculated at less than 0.1 mSv based on low dose CT systems 2. [2] *This represents less than 2% of the dose from a bone scan."* *Joseph Wong*

Further technical enquires should be directed to radiation technologist, Joseph Wong on 07 3357 0333.

Sincerely

Michael Bourke
Assistant Director Physiotherapy – Orthopaedics, QEII Jubilee Hospital

References
1. International Committee on Radiological Protection 80, 1997.
2. Henckel J, Richards R, Lozhkin K, et al. Very low-dose computed tomography for planning and outcome measurement in knee replacement. The imperial knee protocol. Journal of Bone and Joint Surgery - British Volume 2006; 88(11): 1513-1518.

CC: Steve Blackwell, Dr Eric Sclavos (QScan); Joseph Wong (UQ); Peter Buttrum (Director of Physiotherapy QEII); Dr Philip Dalton (Director Orthopaedic Surgery QEII)

Princess Alexandra Hospital
Health Service District

Queensland Government

Queensland **Health**

Enquiries to: PAH Human Research Ethics Committee
Telephone: 3240 7672
TTY: 07 3240 7737
Facsimile: 3240 7667
Email: PAH_Ethics_Researc h@health.qld.gov.au

Our Ref: 2005/191

Date: 7 November 2007

Mr Michael Bourke
Physiotherapy Department
QEII Jubilee Hospita
PMB2
Acacia Ridge 4110

Dear Mr Bourke

Re: 2005/191
An Evaluation of the Clinical Outcomes of the Subvastus Versus the Medial Parapatella Approach to Total Knee Replacement.

On the 5 November 2007 the Princess Alexandra Hospital Human Research Ethics Committee Chair executively reviewed the following amendment(s) for the above study and approval was granted:

- Letter dated 19 October 2007, outlining an amendment to the method of bone scanning to allow better assessment of patella vascularity.

It should be noted that all requirements of the original approval still apply.

If you have any queries, please do not hesitate to contact the Princess Alexandra Hospital Human Research Ethics Committee Executive Support Officer on (07) 3240 7672.

Best wishes for the progress of the study.

Yours sincerely

Ms Gwynneth Petrie
Chair
Human Research Ethics Committee
Princess Alexandra Hospital Health Service District

Appendix 15 Ethics approval - Probability

Princess Alexandra Hospital
Health Service District

Queensland Government

Queensland **Health**

Enquiries to: PAH Human Research Ethics Committee
Telephone: 3240 7672
TTY: 07 3240 7737
Facsimile: 3240 7667
Email: Helen_banks@health.qld.gov.au

Our Ref: 2005/191

Date: 24 January 2007

Mr Michael Bourke
Senior Physiotherapist – Orthopaedics
QEII Jubilee Hospital
PMB 2 Acacia Ridge
BRISBANE QLD 4110

Dear Mr Bourke

Re: 2005/191
Sub-Study - An Evaluation of the Clinical Outcomes of the Subvastus Versus the Medial Parapatella Approach to Total Knee Replacement. An Evaluation of the Clinical Outcomes of the Subvastus Versus the Medial Parapatella Approach to Total Knee Replacement – Comparing Healthy Knees to Those requiring Replacement.

On the 24 January 2007 the Chairperson on behalf of the Princess Alexandra Hospital Human Research Ethics Committee Chair executively reviewed the following amendment(s) for the above study and approval was granted:

- Participant Information Sheet for Healthy Knee Sub-Study Version 1 dated 18/01/2007
- Consent Form for Release for Use of Images or Recordings for Healthy Knee Sub-Study Version 2 dated 24 January 2007

It should be noted that all requirements of the original approval still apply.

If you have any queries, please do not hesitate to contact the Princess Alexandra Hospital Human Research Ethics Committee Executive Support Officer on (07) 3240 7672.

Best wishes for the progress of the sub-study.

Yours sincerely

Ms Gwynneth Petrie
Chair
Human Research Ethics Committee
Princess Alexandra Hospital Health Service District

Office Princess Alexandra Hospital Health Service District
Postal Ipswich Road Woolloongabba Q 4102
Phone 61 7 3240 2111
Fax 61 7 3240 5677

Appendix 16 Participant information and consent forms - Probability

PARTICIPANT INFORMATION SHEET – QEII JUBILEE HOSPITAL

PROJECT TITLE *A comparison of healthy knees to knees requiring total knee arthroplasty. Probability of knee replacement.*

LAY TITLE *Healthy knees compared to knees requiring replacement. Chance of needing a knee replacement.*

INVESTIGATORS *All members of the research team are contactable on 07 3275 6331 where they may be paged by reception staff. The after hours contact is 3275 6111. Michael Bourke's direct contact number is 3275 6173.*

Michael Bourke	Senior Physiotherapist – Orthopaedics, QEII Jubilee Hospital
Peter Buttrum	Director of Physiotherapy, QEII Jubilee Hospital
Linh Ho	Senior Physiotherapist – Orthopaedics, QEII Jubilee Hospital
Dr Trevor Russell	Lecturer, Department of Physiotherapy, University of Queensland.

We would like your help in establishing normal values for healthy knees. The measures from your knee will be compared with people undergoing knee replacement. There are no risks involved in this study.

To be included in this study you must meet the following criteria:

- Age of 18 years or over
- Healthy and no knee pain on a general daily basis
- Ability to accurately follow commands
- Ability to attend a supervised outpatient physiotherapy assessment session
- Ability to participate voluntarily and provide signed informed consent.

You cannot participate in the study if you:

- have medical conditions such as malignant tumours or severe chronic obstructive pulmonary disease that would prevent participation in the required assessment process
- have a previous history of knee surgery
- are unable to follow commands
- cannot walk normally with or without a walking aid.
- are unable to provide signed informed consent
- cannot bend your knee to a right angle

- cannot straighten your knee.

If you agree to participate in the study, you will be required to attend a one hour session at the Physiotherapy Department at the QEII Jubilee Hospital. At this session, the following will occur:

Questions about your ability to function will be asked

You will be required to undergo physical assessments of your knee similar to those normally expected in a knee examination. Such things as knee range of motion, muscle strength and swelling.

None of the assessments performed during the study will cause any pain beyond that normally encountered with physical knee assessment.

For this study you will need to consent for photography of your knee.

Participation in this study is on a voluntary basis and you reserve the right to withdraw at any time from the study for any reason, without any penalty and without affecting any further relations with the QEII Jubilee Hospital.

Your confidentiality will be maintained at all times throughout the study and you will in no way be identified in any publication or report. Furthermore, you will be assigned a number that will be used, rather than your name, on all stored information. All assessment measures will be stored in a lockable cabinet in the Physiotherapy Department at the QEII Jubilee Hospital. Data collected with computer technology will be stored in a password protected secure database in coded format and will be available only to those researchers directly involved in this research. De-identified data will be stored for a maximum of fifteen years upon completion of the study.

A copy of the outcomes of this study will be available from the Physiotherapy Department at the QEII Jubilee Hospital for your interest at the completion of the study in January 2010. Additionally, you are invited to attend QEII Physiotherapy Department on completion of the study where the results of the study will be available.

Both the QEII Jubilee Hospital and the University of Queensland ethics committees have given ethical clearance for this study. You are free to discuss your participation in this study with the project staff on 3275 6173, however, if you would like to speak to an officer not involved in the study, you may contact the Ethics Officer at the University of Queensland on 3365 3924. The

Princess Alexandra Hospital Research Ethics Committee (acting for the QEII Jubilee Hospital) may be contacted on 3240 5856.

By consenting to participate in this study you give members of the research team permission to access your medical record for the purpose of the study if required.

This study is being conducted as part of a requirement for a Masters of Physiotherapy higher research degree at the University of Queensland, Brisbane, Australia.

Photographic Consent Form Information

Important note: Important information explaining this consent is located on the next page of this consent form. You may request a copy of this information at any time.

IMPORTANT PRIVACY INFORMATION:

The Department is collecting the information contained in this form to verify your consent for use of your image or recording for the purposes contained in the consent form. Your consent to the use of your personal information is required in accordance with the Queensland Government's Information Privacy Standard 42. The information privacy principles contained within this Standard govern the collection, use, storage, security, and disclosure of personal information. Only authorised Departmental officers have access to this information. From time to time the Department may provide some or all of this material to other government departments and agencies, or to recognised media outlets for their use to promote Departmental programs, services and initiatives as outlined above. Your personal information contained in this form will not be disclosed to any other third party without your consent, unless authorised or required by law. If you have any queries about any privacy issues that relate to this consent form then please contact the Department's privacy contact officer.

Photographic Consent Form Information

EXPLANATORY NOTES FOR THE PARTICIPANT

What is this consent for?

This consent form authorises the Department to use the specified image or recording of the participant, together with information about their participation in Departmental initiatives, in publications, productions and presentations in connection with the Department's work. The consent

extends to use of the image or recording in whole or part and digital adaptations used alone or in conjunction with words, drawings and other images.

What sort of publications could this material appear in?

This material can appear in television advertising, videos, brochures, forms, public relations displays, annual reports, press advertising, internal documents such as manuals, web sites, certificates, strategic plan, posters and promotional material and other materials produced by the Department. The images and recordings may also be used by other government departments and agencies for similar purposes (if authorised).

What is an image or recording?

An image or recording referred to in this consent form includes photographs, videos, films, or sound recordings of the Participant.

Who is a child?

A child is defined as any person who has not yet turned 18 years of age.

Who is a person with a decision-making disability?

For the purposes of this consent form, a person with a decision making disability is a person who cannot give consent because they lack capacity or have an intellectual or other impairment that affects their capacity to consent. If a person is an adult and unable to give consent, an authorised decision-maker must give consent on the person's behalf (see for example *Powers of Attorney Act 1998* and/or the *Guardianship and Administration Act 2000*).

What happens to the consent form once it is filled out?

The consent form is retained by the Department and will be placed on file. A copy will be provided to the Participant.

Modification or Withdrawal of consent

Consent can be modified or withdrawn in writing at any time however, any changes will only apply from the date of receipt by the Department. Any existing material in which the image or recording is used will not be withdrawn from use.

Produced by Media and Communication Unit, Queensland Health

Queensland Government
Queensland Health

CONSENT FORM FOR PARTICIPATION IN STUDY

PROJECT TITLE	***A comparison of healthy knees to knees requiring total knee arthroplasty.***	
LAY TITLE	***Healthy knees compared to knees requiring replacement.***	
INVESTIGATORS	*Michael Bourke*	Senior Physiotherapist – Orthopaedics, QEII Jubilee Hospital
	Peter Buttrum	Director of Physiotherapy, QEII Jubilee Hospital
	Linh Ho	Senior Physiotherapist – Orthopaedics, QEII Jubilee Hospital
	Dr Trevor Russell	Lecturer, Department of Physiotherapy, University of Queensland

QEII JUBILEE HOSPITAL

I _____ *(print name)* consent to take part in the above study.

I have read the attached Participant Information Sheet. I understand the nature and purpose of this study. I understand that there are no side-effects or risks involved. All my questions have been answered to my satisfaction.

I acknowledge that my involvement in the study may not be of benefit to me.

The opportunity has been given to me to have a friend or relative present when the study was explained.

I understand that taking part in the study is voluntary and I am free to withdraw at any time

I give permission for the research team to access my medical record.
I understand that all the information gained in the study will be treated confidentially.

Participant: _____ Print name:_____ Date:___/___/___

Witness:_____ Print name:_____ Date:___/___/___

I have explained the nature and purpose of this study to the above participant and have answered their questions.

Investigator: _____ Date:_____

Appendix 17 Logistic regression models – Stata 10.0 output

Models highlighted in yellow

```
. * GENERATE A VARIABLE FOR CASES AND CONTROL *
.
. gen case_control=1 if group==2
(42 missing values generated)

. replace case_control=0 if group==1
(42 real changes made)

.
. * LOOK AT THE CORRELATION MATRIX INCLUDING ALL VARIABLES *
.
. corr   gkp  maxflx ke truelag tug oxford akssobj akssfun
(obs=84)

             |      gkp   maxflx       ke  truelag      tug   oxford  akssobj  akssfun
-------------+------------------------------------------------------------------------
         gkp |   1.0000
      maxflx |  -0.6642   1.0000
          ke |   0.5900  -0.5321   1.0000
     truelag |   0.0245  -0.0963  -0.0311   1.0000
         tug |   0.7213  -0.6175   0.4874   0.1227   1.0000
      oxford |   0.8512  -0.7417   0.6585   0.1321   0.7817   1.0000
     akssobj |  -0.9310   0.7247  -0.6951  -0.1044  -0.6926  -0.8660   1.0000
     akssfun |  -0.7552   0.6533  -0.6094  -0.1930  -0.7630  -0.8723   0.7947   1.0000


.
. * FIT UNIVARIATE LOGISTIC REGRESSION MODELS ONE BY ONE
.
. logistic  case_control gkp

note: gkp != 1 predicts success perfectly
      gkp dropped and 40 obs not used


Logistic regression                               Number of obs   =         44
                                                  LR chi2(0)      =      -0.00
                                                  Prob > chi2     =          .
Log likelihood = -8.1359256                       Pseudo R2       =    -0.0000

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
------------------------------------------------------------------------------

. logistic  case_control maxflx

Logistic regression                               Number of obs   =         84
                                                  LR chi2(1)      =      65.85
                                                  Prob > chi2     =     0.0000
Log likelihood = -25.298399                       Pseudo R2       =     0.5655

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
      maxflx |   .7940135   .0405615    -4.52   0.000     .7183646    .8776287
------------------------------------------------------------------------------

. logistic  case_control ke

Logistic regression                               Number of obs   =         84
```

```
                                                LR chi2(1)      =      61.84
                                                Prob > chi2     =     0.0000
Log likelihood =  -27.30565                     Pseudo R2       =     0.5310

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
          ke |   1.957467   .2782028     4.73   0.000     1.481557     2.58625
------------------------------------------------------------------------------

. logistic  case_control  truelag

Logistic regression                             Number of obs   =         84
                                                LR chi2(1)      =       0.83
                                                Prob > chi2     =     0.3623
Log likelihood = -57.809372                     Pseudo R2       =     0.0071

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     truelag |   1.078102   .0897547     0.90   0.366     .9157887    1.269184
------------------------------------------------------------------------------

. logistic  case_control  tug

Logistic regression                             Number of obs   =         84
                                                LR chi2(1)      =      79.17
                                                Prob > chi2     =     0.0000
Log likelihood = -18.640182                     Pseudo R2       =     0.6799

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         tug |   3.460932   1.054232     4.08   0.000     1.905062    6.287485
------------------------------------------------------------------------------

. logistic  case_control oxford
outcome = oxford > 17 predicts data perfectly
r(2000);

end of do-file

r(2000);

. logistic  case_control akssobj

Logistic regression                             Number of obs   =         84
                                                LR chi2(1)      =     103.78
                                                Prob > chi2     =     0.0000
Log likelihood = -6.3362591                     Pseudo R2       =     0.8912

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssobj |   .5404446   .1358372    -2.45   0.014      .330223    .8844943
------------------------------------------------------------------------------
Note: 0 failures and 11 successes completely determined.

. logistic  case_control akssfun

Logistic regression                             Number of obs   =         84
                                                LR chi2(1)      =      85.42
                                                Prob > chi2     =     0.0000
Log likelihood = -15.515001                     Pseudo R2       =     0.7335

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .8381752   .0350472    -4.22   0.000     .7722234    .9097596
------------------------------------------------------------------------------
```

```
.
. *gen lngkp=ln(gkp)
. *logistic  case_control lngkp
.
. * LOOK AT THE MODEL WITH AKS OBJECTIVE AS THE PREDICTOR
.
. logistic  case_control akssobj

Logistic regression                                     Number of obs   =         84
                                                        LR chi2(1)      =     103.78
                                                        Prob > chi2     =     0.0000
Log likelihood = -6.3362591                             Pseudo R2       =     0.8912

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssobj |   .5404446   .1358372    -2.45   0.014      .330223    .8844943
------------------------------------------------------------------------------
Note: 0 failures and 11 successes completely determined.

.
. * TRY OBJECTIVE AND FUNCTIONAL IN THE SAME MODEL
. * THIS BREAKS DOWN BECAUSE THE TWO VARIABLES ARE STRONGLY CORRELATED
.
. logistic  case_control akssobj akssfun

Logistic regression                                     Number of obs   =         84
                                                        LR chi2(2)      =     116.45
                                                        Prob > chi2     =     0.0000
Log likelihood = -6.773e-08                             Pseudo R2       =     1.0000

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssobj |   .0008897    1.42557    -0.00   0.997            0           .
     akssfun |   .2440843   134.5514    -0.00   0.998            0           .
------------------------------------------------------------------------------
Note: 41 failures and 40 successes completely determined.

.
.
. * START AGAIN USING AKS FUNCTIONAL AS THE FIRST INDEPENDANT VARIABLE
.
. logistic  case_control akssfun

Logistic regression                                     Number of obs   =         84
                                                        LR chi2(1)      =      85.42
                                                        Prob > chi2     =     0.0000
Log likelihood = -15.515001                             Pseudo R2       =     0.7335

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .8381752   .0350472    -4.22   0.000     .7722234    .9097596
------------------------------------------------------------------------------


.
.
. * NOW ADD KNEE EXTENSION TO THE MODEL
. * THIS IS MODEL 1
.
. logistic  case_control akssfun ke

Logistic regression                                     Number of obs   =         84
                                                        LR chi2(2)      =     105.38
                                                        Prob > chi2     =     0.0000
Log likelihood = -5.5334376                             Pseudo R2       =     0.9050

------------------------------------------------------------------------------
```

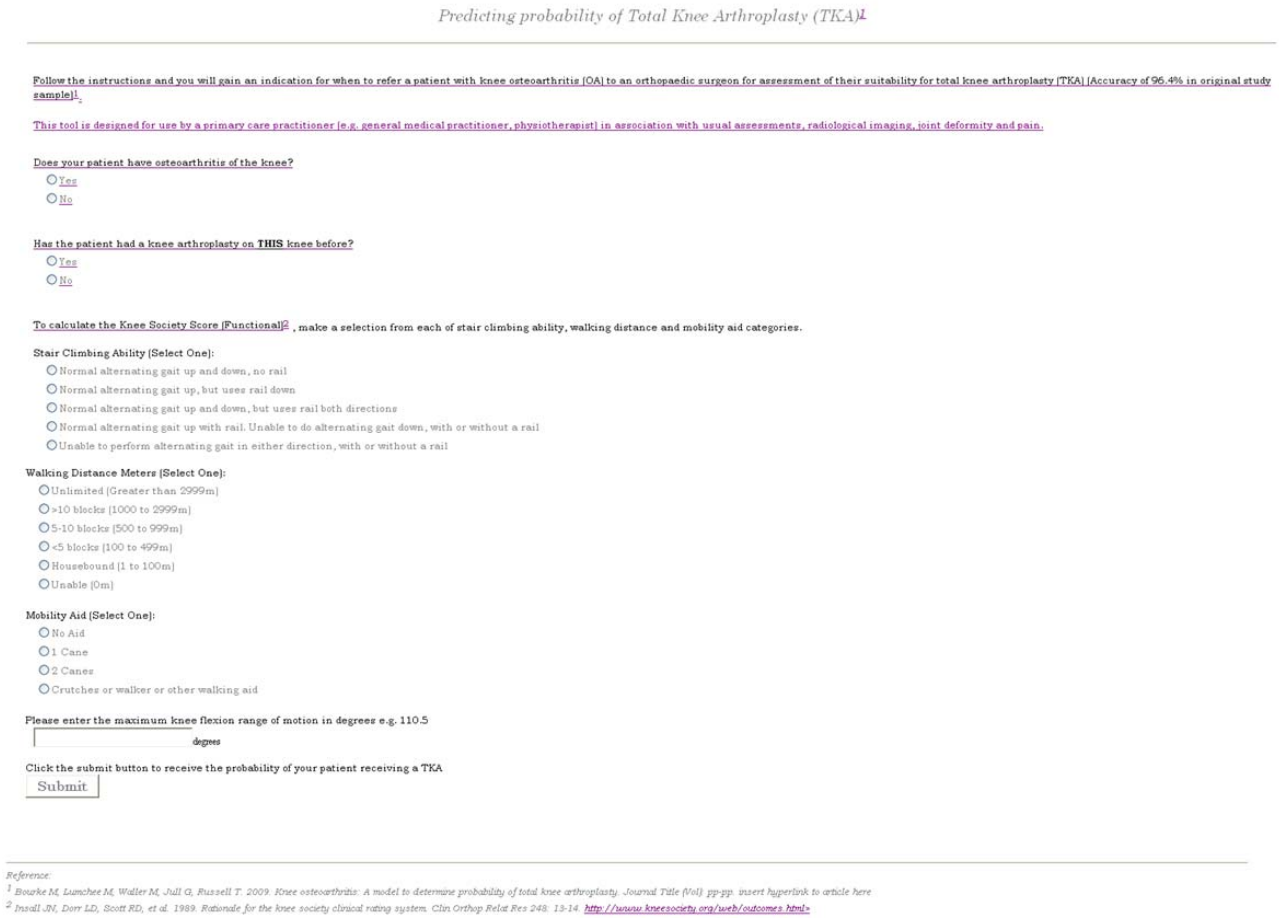
```
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .7662152   .0958762    -2.13   0.033     .5995705    .9791771
          ke |   2.160413   .7123772     2.34   0.019     1.132037    4.122997
------------------------------------------------------------------------------
Note: 0 failures and 7 successes completely determined.

. predict  prob1
(option pr assumed; Pr(case_control))

.
. * NOW ADD MAXFLEX INSTEAD OF KNEE EXTENSION
. * THIS IS MODEL 4
.
. logistic  case_control akssfun maxflx

Logistic regression                               Number of obs   =         84
                                                  LR chi2(2)      =      98.58
                                                  Prob > chi2     =     0.0000
Log likelihood = -8.9323456                       Pseudo R2       =     0.8466

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .8665039   .0385575    -3.22   0.001     .7941343    .9454685
      maxflx |   .7830936   .0930401    -2.06   0.040     .6204141    .9884295
------------------------------------------------------------------------------

. predict  prob4
(option pr assumed; Pr(case_control))

.
. * NOW HAVE AKS FUNCTIONAL, KNEE EXTENSION and MAXFLUX IN THE MODEL
. * THIS MODEL HAS VERY LARGE ODDS RATIOS
.
. logistic  case_control akssfun ke maxflx

Logistic regression                               Number of obs   =         84
                                                  LR chi2(3)      =     116.45
                                                  Prob > chi2     =     0.0000
Log likelihood = -1.600e-08                       Pseudo R2       =     1.0000

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .0014209          .        .       .            .           .
          ke |   3.17e+07          .        .       .            .           .
      maxflx |   .0344765   1.939003    -0.06   0.952     4.62e-50    2.57e+46
------------------------------------------------------------------------------
Note: 41 failures and 42 successes completely determined.

.
. * NOW CONSIDER THE MODEL WITH AKS FUNCTIONAL KE and TUG
. * IN THIS MODEL TUG IS NOT SIGNIFICANT
.
. logistic  case_control akssfun ke tug

Logistic regression                               Number of obs   =         84
                                                  LR chi2(3)      =     110.92
                                                  Prob > chi2     =     0.0000
Log likelihood = -2.7667095                       Pseudo R2       =     0.9525

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .8360005   .1142184    -1.31   0.190     .6396042    1.092702
          ke |   3.122065   2.429613     1.46   0.143     .6792521    14.35003
         tug |   8.372278    16.6397     1.07   0.285     .1702555    411.7049
------------------------------------------------------------------------------
Note: 4 failures and 21 successes completely determined.
```

```
. predict probnew
(option pr assumed; Pr(case_control))

.
. * NOW CONSIDER THE MODEL WITH AKS FUNCTIONAL KE and TRUELAG
. * IN THIS MODEL TRUELAG IS NOT SIGNIFICANT
.
. logistic  case_control akssfun ke truelag

Logistic regression                               Number of obs   =         84
                                                  LR chi2(3)      =     105.39
                                                  Prob > chi2     =     0.0000
Log likelihood = -5.5289614                       Pseudo R2       =     0.9050

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .7611958   .1126729    -1.84   0.065     .5695093    1.017401
          ke |   2.164031   .7248356     2.30   0.021     1.122422    4.172255
     truelag |   .9632084   .3844963    -0.09   0.925     .4404891    2.106228
------------------------------------------------------------------------------
Note: 0 failures and 7 successes completely determined.

. predict probnew1
(option pr assumed; Pr(case_control))

.
. * NOW CONSIDER THE MODEL WITH AKS FUNCTIONAL KE TRUELAG and TUG
. * THIS MODEL HAS VERY LARGE ODDS RATIOS
.
. logistic  case_control akssfun ke tug truelag

Logistic regression                               Number of obs   =         84
                                                  LR chi2(4)      =     116.45
                                                  Prob > chi2     =     0.0000
Log likelihood = -3.420e-08                       Pseudo R2       =     1.0000

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
     akssfun |   .0309871   2.209038    -0.05   0.961     6.46e-63    1.49e+59
          ke |   2.20e+07          .        .       .            .           .
         tug |   1.74e+15          .        .       .            .           .
     truelag |   3.30e-07   .0012359    -0.00   0.997            0           .
------------------------------------------------------------------------------
Note: 41 failures and 41 successes completely determined.

.
.
. corr akssobj akssfun
(obs=84)

             |  akssobj  akssfun
-------------+------------------
     akssobj |   1.0000
     akssfun |   0.7947   1.0000


.
. * NOW BUILD MODEL AGAIN STARTING FROM maximum flex *
.
. logistic  case_control maxflx

Logistic regression                               Number of obs   =         84
                                                  LR chi2(1)      =      65.85
                                                  Prob > chi2     =     0.0000
Log likelihood = -25.298399                       Pseudo R2       =     0.5655

------------------------------------------------------------------------------
```

```
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
      maxflx |   .7940135   .0405615    -4.52   0.000     .7183646    .8776287
------------------------------------------------------------------------------

.
. * NOW MODEL WITH KE AND MAXFLX THIS IS MODEL 2
. logistic  case_control ke maxflx

Logistic regression                               Number of obs   =         84
                                                  LR chi2(2)      =      88.68
                                                  Prob > chi2     =     0.0000
Log likelihood = -13.886774                       Pseudo R2       =     0.7615

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
          ke |   1.780432    .319818     3.21   0.001     1.252059    2.531782
      maxflx |   .8296008   .0450093    -3.44   0.001     .7459127    .9226785
------------------------------------------------------------------------------

. predict prob2
(option pr assumed; Pr(case_control))

.
. * THE MODEL WITH KE MAXFLX AND AKS FUNCTIONAL HAS LARGE ORS
. logistic  case_control ke maxflx akssfun

Logistic regression                               Number of obs   =         84
                                                  LR chi2(3)      =     116.45
                                                  Prob > chi2     =     0.0000
Log likelihood = -1.600e-08                       Pseudo R2       =     1.0000

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
          ke |   3.17e+07          .        .       .            .           .
      maxflx |   .0344765   1.939003    -0.06   0.952     4.62e-50    2.57e+46
     akssfun |   .0014209          .        .       .            .           .
------------------------------------------------------------------------------
Note: 41 failures and 42 successes completely determined.

.
. * THE MODEL WITH KE MAXFLX AND TRUE LAG THIS IS MODEL 3
. logistic  case_control ke maxflx truelag

Logistic regression                               Number of obs   =         84
                                                  LR chi2(3)      =      91.53
                                                  Prob > chi2     =     0.0000
Log likelihood = -12.461451                       Pseudo R2       =     0.7860

------------------------------------------------------------------------------
case_control | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
          ke |   2.144537   .5647034     2.90   0.004     1.279952    3.593135
      maxflx |   .8084275   .0546322    -3.15   0.002     .7081386    .9229197
     truelag |   1.526829   .3997034     1.62   0.106     .9140234     2.55049
------------------------------------------------------------------------------

. predict prob3
(option pr assumed; Pr(case_control))

.
. sort prob1

.
. browse givenname surname case_control prob1 prob2 prob3 prob4 probnew probnew1
```

Appendix 18 Website for calculating probability of TKA

A web page that calculates the probability of TKA using KSS(Fun)/flexion is provisionally located http://www.uq.edu.au/tru/tkrprob/



Predicting probability of Total Knee Arthroplasty (TKA)[1]

Follow the instructions and you will gain an indication for when to refer a patient with knee osteoarthritis [OA] to an orthopaedic surgeon for assessment of their suitability for total knee arthroplasty [TKA] [Accuracy of 96.4% in original study sample][1].

This tool is designed for use by a primary care practitioner [e.g. general medical practitioner, physiotherapist] in association with usual assessments, radiological imaging, joint deformity and pain.

Does your patient have osteoarthritis of the knee?
- Yes
- No

Has the patient had a knee arthroplasty on **THIS** knee before?
- Yes
- No

To calculate the Knee Society Score [Functional][2], make a selection from each of stair climbing ability, walking distance and mobility aid categories.

Stair Climbing Ability (Select One):
- Normal alternating gait up and down, no rail
- Normal alternating gait up, but uses rail down
- Normal alternating gait up and down, but uses rail both directions
- Normal alternating gait up with rail. Unable to do alternating gait down, with or without a rail
- Unable to perform alternating gait in either direction, with or without a rail

Walking Distance Meters (Select One):
- Unlimited (Greater than 2999m)
- >10 blocks (1000 to 2999m)
- 5-10 blocks (500 to 999m)
- <5 blocks (100 to 499m)
- Housebound (1 to 100m)
- Unable (0m)

Mobility Aid (Select One):
- No Aid
- 1 Cane
- 2 Canes
- Crutches or walker or other walking aid

Please enter the maximum knee flexion range of motion in degrees e.g. 110.5

degrees

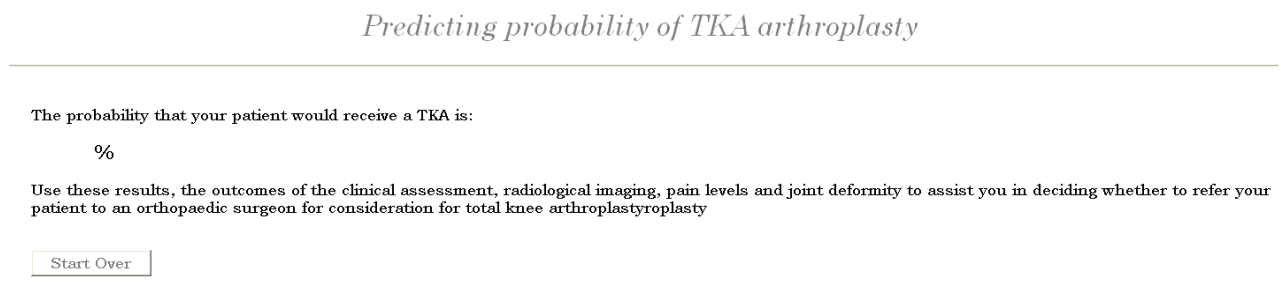
Click the submit button to receive the probability of your patient receiving a TKA

Submit

Reference:

[1] Bourke M, Lumchee M, Waller M, Jull G, Russell T. 2009. Knee osteoarthritis: A model to determine probability of total knee arthroplasty. Journal Title (Vol): pp-pp. insert hyperlink to article here

[2] Insall JN, Dorr LD, Scott RD, et al. 1989. Rationale for the knee society clinical rating system. Clin Orthop Relat Res 248: 13-14. http://www.kneesociety.org/web/outcomes.html»



Predicting probability of TKA arthroplasty

The probability that your patient would receive a TKA is:

%

Use these results, the outcomes of the clinical assessment, radiological imaging, pain levels and joint deformity to assist you in deciding whether to refer your patient to an orthopaedic surgeon for consideration for total knee arthroplastyroplasty

Start Over